ジクロロメタンのラットを用いた吸入によるがん原性試験報告書

試験番号:0278

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APPENDIX A1

CLINICAL OBSERVATION: SUMMARY, RAT: MALE

(2-YEAR STUDY)

STUDY NO.: 0278

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admini:	stration W	eek-day											
		1-1	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
		1	1	1	1	1	1	1	1	1	. 1	1	1	1	1
DEATH	Control	0	0	0	0	0	^	0	^	•					
DENTII	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0			0	0	0	0	0	0	0	0	0
		-			0	0	0	0	0	0 -	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	.0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	Ō	0	Ö	ŏ	Ŏ	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	Ö	Ö	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	^	
	1000 ppm	ő	0	0	Ö	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	-	-	•	-	0	0
	4000 ppm	0	0	0	0	0	. 0	0	0	0	0	0	0	0	0
	1000 ppili	V	v	V	V	V .	. 0	V	Ü	U	0	U	0	0	0
ATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	ő
	2000 ppm	0	0	0	0	0	0	0	0	0	0	o o	0	0	0
	4000 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	•
	1000 ppm	Ö	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	Ö	0	Ö	Ő	0	0	0	0	0	0	0	-	•	0
	4000 ppm	0	0	Õ	Ö	0	0	0	0	0	0	0	0	0	0
ACTING	.	•		_								·	v	v	v
VASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0 .	0	0	0	0	0	0	0
OILED	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	Ö	Ŏ	ŏ	Ö	0	0	0	0	0	0	0	0	0
	2000 ppm	Ô	0	0	0	Ő	0	0	0	0	0	0		•	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		v	•	•	•	v	V	v	U	U	U	U	U	U	0
ILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ŏ	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	ő	Ö	0
	4000 ppm	0	0	0	0	0	0	0	0	Ô	0	0	0	0	0

STUDY NO.: 0278 ANIMAL: RAT F344/DuCrj

REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Adminis	stration W	eek-day _											
		14-7	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
		1	1	1	1	1 .	1	1	1	1	1	1	1	1	1
ЕАТН	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATH	1000 ppm	0	0	0	0	ů	Ő	0	Ô	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	Ö	Ö	ő	0	Ö	0	0	0	0	0	0
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	. 0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0278 CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admini	stration W	leek-day											
		28-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0 .	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0.	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCONOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ō
PARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	Ö	0	Õ	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	Ö	0	0	0
SOILED	Control	0	0	0	0	0	0	0	0	0	0	0	.0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	Ŏ	0	Õ	0
	2000 ppm	0	0	0	0	0	ō	Ö	0	Ö	0	ő	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	Ö	ő	Õ	0	Ô	0
	2000 ppm	0	0	0	0	0	0	Ö	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	Ö	Ŏ	ő	0	0	0	0	0	0	0

STUDY NO.: 0278

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-day											
	•	42-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
D. 771							_	_							
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0 .	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ARALYTIC GAIT	Control	0	0	0	0	0	0	, 0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	Ö	Ô	0	Ö	0
OILED	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	Ô	0	0
	2000 ppm	0	0	0	0	Ö	Ö	Ŏ	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	. 0	0	0	0	ő	0	Ŏ	0
ILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	Ō	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	ő
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	ŏ

STUDY NO. : 0278
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admini	istration W	leek-day _											
		56-7	57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	Combood	0	0	٥	^	0	0	^	٥	•	•	0	•	•	•
DENTIL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0 0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	Ü	U	0	U	0	0	0	0	0	0	0	0	0	0
ORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	- 0	0	0	0	0	0	0
OCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATERAL	Contral	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0 .	0	0	0	0	0	0	0	0	0	0
ARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OILED	Cantrol	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	Ö	0	Ö	0
ILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	Ö	0	0	Ö	0
	2000 ppm	0	0	0	0	0	0	. 0	Ô	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	Ö	0	0	0	0	0	0	0	0

STUDY NO.: 0278

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admini	istration W	leek-day											
		70-7	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
	•••	1	1	1	1	1	1	1	1	1	1	1	1	1	1
реатн Тамин тамин там	Control	0	0	0	1	1	1	1	,	t	1	1	0	0	0
ZAT II	1000 ppm	0	0	1	1		1	1	1	1	1	1	2	2	2
	2000 ppm	0	0	0	0	1 0	1	1		1	1	1	2	2	2
	4000 ppm	1	1	1	2	2	2	0 3	0 4	0 4	0 4	0 4	0 4	0 5	0 5
ORIBUND SACRIFICE	Control	0	0	1	1	1	1	1	1	1	2	2	2	2	2
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	1	i	1	1	1	1	1	2	2
	4000 ppm	0	0	0	0	0	0	0	ō	ō	ō	Ô	Ō	Ö	0
OCOMOTOR MOVEMENT DECR	Contral	0	1	0	0	0	0	0	0	0	1	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ō	0
	4000 ppm	0	0	0	0	0	1	0	0	0	0	0	0	0	0
ATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	. 0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
VASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
COILED	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	Ó	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	c	0	0	0	0	0	0	0	0

STUDY NO.: 0278

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : MALE

linical sign	Group Name		stration W												
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
EATH	Control	2	9	o	o	2	9	2	4	4	4	F	0	•	2
EAIR			2	2	3	3	3	3	4	4	4	5	6	6	6
	1000 ppm	2	2 0	2	2	2	2	2	2	2	2	2	3	3	3
	2000 ppm	0 7	7	0 7	0 7	1 7	1 7	1 7	1	1	1	1	2	2	3
	4000 ppm	1	,	,	1	7	,	1	7	8	8	9	11	11	11
DRIBUND SACRIFICE	Control	2	2	2	4	5	5	5	6	6	6	6	6	6	7
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	2000 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	2
OCOMOTOR MOVEMENT DECR	Control	0	0	1	1	1	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ô
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
TERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
RALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	1	1	1	2	2	1	1	1	2
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
STING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
DILED	Control	0	0	0	0	0	0	0	0	0	1	1	0	0	0
	1000 ppm	0	0	0	0	0	1	1	1	1	1	1	1	i	0
	2000 ppm	0	0	0	0	0	0	0	0	ō	0	Ô	0	Ô	ő
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOERECTION	Control	0	0	0	1	1	0	0	0	0	1	1	0	0	0
	1000 ppm	0	0	0	0	0	1	1	Ĭ	ĺ	î	î	I	1	ő
	2000 ppm	6	0	0	Ō	0	0	้	0	Ô	Ô	Ô	Ô	0	0
	4000 ppm	0	0	0	0	ĵ	0	0	Ö	ő	0	0	0	1	0

STUDY NO.: 0278

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admini	istration !	Week-day _					
		98-7	99-7	100-7	101-7	102-7	103-7	104-7	
		1	1	1	1	1	1	1	
DEATH	Control	6	6	6	6	6	6	7	
	1000 ppm	3	3	3	3	4	4	4	
	2000 ppm	4	4	4	4	4	4	4	
	4000 ppm	11	11	13	15	17	17	18	
	1000 ppm	••	**	10	10	1.	1.	10	
MORIBUND SACRIFICE	Control	7	7	7	8	8	11	11	
	1000 ppm	3	3	3	3	3	3	3	
	2000 ppm	2	2	3	4	5	7	8	
	4000 ppm	3	3	3	3	3	3	4	
	TOOU PPIII	Ü	J	Ü	J	3	J	4	
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	1	0	1	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	0	0	1	1	1	2	1	
	4000 ppm	1	0	0	0	0	0	ì	
					-	-	-	-	
LATERAL	Control	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	
	4000 ppm	0	0	Ö	Ö	Ö	ő	0	
PARALYTIC GAIT	Control	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	
	4000 ppm	0	0	0	0	0	0	0	
HICTING	a	•			_	_			
WASTING	Control	0	0	0	0	0	1	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	1	0	
	4000 ppm	1	0	0	0	0	0	0	
SOILED	Control	٨	۸	^	0	0	0	^	
SOTEED		0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	
	4000 ppm	0	0	0	0	0	0	0	
PILOERECTION	Control	0	0	0	0	0	0	0	
1 IDOLALOI I UN	1000 ppm	0	0	0	0	0			
					•		0	0	
	2000 ppm	0	0	0	0	0	0	0	
	4000 ppm	0	0	0	0	0	C	0	
(71114.00)	·								

STUDY NO. : 0278

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-day											
		1-1	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
That bell u	0	•													
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
	2000 ppm	0	0	0	0	0	0	0	0	0	0	Ō	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0.	Ö	ŏ	0	0	0	0
EYE OPACITY	Control	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	Õ	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	Ö	Ö	Ö	Ö	0	0	0	0
CATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	Ö	Ŏ	0	0	0
	2000 ppm	0	0	0	Ō	Ö	0	o O	0	0	0	Ö	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	Ö	Ö	0	0	0	0
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	Ö	0	Ö	Ö	ő	Ö	0	0	0	0	0	0	0	0
	2000 ppm	0	0	Ö	ő	0	0	0	0	0	0	0	0	0	
	4000 ppm	ő	Ö	0	0	0	0	0	0	0	0	0	0	0	0 0
INTERIOS CHAMBER OPACITY	Control	0	1	0	0	0	0	0	0	0	0	0	0	0	٨
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	•	0
	4000 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	^
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0		0	-	-	-	-	•	0	0
		0	0	0	0	0	Ú		0	0	0	0	0	0	0
	4000 ppm	U	v	U	U	()	0	0	0	0	C	0	0	0	0

STUDY NO. : 0278 ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

SEX: MALE

Clinical sign	Group Name	Admini	stration W	leek-day _											
		14-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
FROG BELLY	Control	٥		٥	0	۰	•	•	•	•	•				
PROG DELLI	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
XOPHTHALMOS	Control	0	0	0	0	0	. 0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
YE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	2000 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	ĩ
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	Ö	1	1	1	1	1
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	ō	0
ORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	Ö	0	Ö	Ö	Ö	ő	0	Ő	0
	2000 ppm	0	0	0	0	Ö	0	0	ŏ	Ö	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	Ö	ő	Ö	0	0	0	0	0
NTERIOS CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	Ö	Ö	Ŏ	0	Õ	0	0	0	0	0
	2000 ppm	0	0	Ö	0	0	0	Ö	ő	0	0	0	0	0	0
	4000 ppm	Ŏ	Ö	0	0	0	0	Ö	Ö	0	0	0	0	0	0
XTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	Ö	ů	0	ő	0	0	0	0	0	0	0
	2000 ppm	0	0	0	Ö	Ô	0	Ö	0	0	0	0	0	0	0
	4000 ppm	0	0	Ů.	0	0	Ö	ő	0	0	C	0	0	0	0

STUDY NO. : 0278

CLINICAL OBSERVATION (SUMMARY)

ANIMAL : RAT F344/DuCrj ALL ANIMALS REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name		stration W												
		28-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
ROG BELLY	Centrol	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	Ö	ŏ	0	Ö	Ö	0	Ö	0	0	0	0	0	0	0
DILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
XOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
E OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	1	1	1	1	1	1	1	0	0	0	1	1	1	2
	2000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	2000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NTERIOS CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
XTERNAL MASS	Control	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	Ü	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	С	0	0	0	0

STUDY NO. : 0278

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-day											
-		42-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
inos pur i v										_					
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	.0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPIITHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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	1	1	1	1	1
	1000 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	2000 ppm	1	1	1	2	2	2	2	2	2	2	2	2	2	2
	4000 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	1	1	1	i	1
	1000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	2000 ppm	1	1	1	2	2	2	2	2	2	2	2	2	2	2
	4000 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
	1000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ô	. 0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
ANTERIOS CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
	2000 ppm	Ō	0	0	Ö	0	Ö	0	Ö	0	Ö	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	Ö	Ö	0	Ö	0
EXTERNAL MASS	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	1000 ppm	0	0	0	0	0	1	1	1	1	1	1	1	1	1
	2000 ppm	1	1	1	1	1	ī	1	4	$\hat{4}$	2	3	3	3	3
	4000 ppm	0	0	Ô	0	0	0	Ô	0	1	1	1	0	0	0

STUDY NO.: 0278

ANIMAL: RAT F344/DuCrj
REPORT TYPE: A1 104

Group Name

2000 ppm

4000 ppm

Control

1000 ppm

2000 ppm

1000 ppm

SEX : MALE

Clinical sign

-		56-7	57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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	2
	1000 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	2000 ppm	2	2	2	2	2	2	3	3	3	3	3	3	3	3
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	2
	1000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	2000 ppm	2	2	2	2	2	2	3	3	3	3	3	3	3	3
	4000 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
	1000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTERIOS CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0000		_	_	_	_	_	_							

Administration Week-day _____

EXTERNAL MASS

STUDY NO. : 0278 ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : MALE PAGE: 14

Clinical sign	Group Name	Admini	stration W	eek-day											
		70-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
noc perty	Comboni	^		0	•	•	•		•						_
ROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	1	0	0	0	0	0	0	0	1	1	1	1
DILED PERI GENITALIA	Control	0	1	0	0	0	0	0	0	0	1	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	2000 ppm	0	0	0	1	1	0	0	0	0	0	0	1	1	0
	4000 ppm	0	0	0	0	0	1	0	0	0	0	0	0	0	0
XOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
YE OPACITY	Control	2	2	2	2	2	2	2	. 2	2	2	2	2	2	2
	1000 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	2000 ppm	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATARACT	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	1000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	2000 ppm	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	4000 ppm	0	0	0	0	0	0	0	0	Ō	0	0	0	0	0
ORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	1	1	1	1	i	1	1	1	1	1	1	1	I	1
	2000 ppm	Ō	0	0	0	0	0	0	Ô	Ô	Ô	0	0	ô	0
	4000 ppm	0	0	Ō	0	Ŏ	Ö	0	0	Ö	Ö	Ö	0	0	0
NTERIOS CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	Õ	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	Ŏ	Ö	Ő	0	0	0	0	0	0	0	0	0	0
	4000 ppm	ŏ	Ö	Ö	0	ŏ	ő	0	ő	Ö	0	0	0	0	0
XTERNAL MASS	Control	3	3	3	3	3	3	3	3	3	3	3	2	2	2
	1000 ppm	0	0	0	ő	ì	1	1	1	1	1	2	1	1	1
	2000 ppm	4	4	6	6	6	5	5	5	5	6	5	5	5	6
	4000 ppm	ŝ	3	3	3	4	4	4	4	4	4	5	5	6	7

STUDY NO.: 0278
ANIMAL: RAT F344/DuCrj
REPORT TYPE: A1 104

SEX : MALE

Clinical sign	Group Name	Admini	istration W	leek-day _											
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1 -
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	٥	0	۸		•
ROG DELLI	1000 ppm	0			-					0	0	0	0	0	0
	• •	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	2000 ppm 4000 ppm	0	0	0	0	0 0	0	0 0	0	0	0	0	0	0 0	0 0
SOILED PERI GENITALIA	Control	0	0	1	0	0	0	0	0	0	1	1	0	ī	0
	1000 ppm	0	0	0	0	Ö	ŏ	Ö	0	0	Ô	0	0	Ô	0
	2000 ppm	Ö	Ö	ő	0	Ö	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	ő	0	0	ő	ő	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	. 0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	. 0
	2000 ppm	0	0	1	1	1	1	1	1	1	1	i	1	1	i
	4000 ppm	0	0	0	0	0	0	0	Ō	Ō	ô	Ō	Ō	ō	0
EYE OPACITY	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	1000 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	2000 ppm	3	3	3	3	3	3	3	3	4	4	4	4	4	4
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	1000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	2000 ppm	3	3	3	3	3	3	3	3	4	4	4	4	4	4
	4000 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
	1000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	2000 ppm	0	0	0	0	0	0	0	. 0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERIOS CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	2	2	2	1	2	2	3	4	4	4	4	4	5	5
	1000 ppm	1	1	1	3	3	5	5	5	6	6	7	8	11	11
	2000 ppm	6	7	7	8	8	9	9	9	9	9	9	9	9	10
	4000 ppm	6	8	10	12	13	15	16	16	16	16	16	15	15	17

STUDY NO.: 0278

ANIMAL : RAT F344/DuCrj

REPORT TYPE: A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX: MALE

	Group Name	Admini	stration	Week-day _					
		98-7	99-7	100-7	101-7	102-7	103-7	104-7	
		1	1	1	1	1	1	1	
FROG BELLY	Control	0	0	0	0	0	0	0	
	1000 ppm	1	1	1	1	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	
	4000 ppm	0	0	0	0	0	0	0	
SOILED PERI GENITALIA	Control	0	0	0	0	i	0	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	0	1	2	1	0	0	0	
	4000 ppm	0	0	1	1	0	0	0	
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	1	1	1	1	1	1	1	
	4000 ppm	0	0	0	0	0	0	0	
EYE OPACITY	Control	2	2	2	2	2	2	2	
	1000 ppm	2	2	2	2	2	2	2	
	2000 ppm	4	4	4	4	3	3	3	
	4000 ppm	1	0	0	0	0	0	0	
CATARACT	Control	2	2	2	2	2	2	2	
	1000 ppm	1	1	1	1	1	1	1	
	2000 ppm	4	4	4	4	3	3	3	
	4000 ppm	0	0	0	0	0	0	0	
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	
	1000 ppm	1	1	1	1	1	1	1	
	2000 ppm	0	0	0	0	0	0	0	
	4000 ppm	1	0	0	0	0	0	0	
ANTERIOS CHAMBER OPACITY	Control	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	
	4000 ppm	0	0	0	0	0	0	0	
EXTERNAL MASS	Control	5	5	6	7	6	6	5	
	1000 ppm	11	11	11	11	12	13	14	
	2000 ppm	11	11	10	9	<u>i 1</u>	11	10	
	4000 ppm	15	17	16	18	17	17	16	

STUDY NO.: 0278 ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admini:	stration We	eek-day											
		1-1	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
		1	1	1	1	1	1	1	1	1	1	. 1	1	1	1
			٠												
NTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0 .	0	0	0	0	0	0	0	0	0	0	0	0
.NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I.EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0 .	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Y. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ō
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ô	Ö
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	Ũ	C	0	0	0	C	0	Ô	0	Ö

STUDY NO. : 0278

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

MEIONI THE . AT 104

SEX : MALE

Clinical sign	Group Name		stration W												
		14-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
NTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	٥	0
WILMING MAGO	1000 ppm	0	0	0	0	0	0	0				-		0	0
	2000 ppm	0	0	0	0	0	0 -	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0 0	0 0	0 0
I.NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	Ō	0	0	0	0	0	Ö	0	Ö	0
	4000 ppm	0	0	0	0	0	0	0	0	Ō	0	Ö	Ö	Ö	0
M.PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I.EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	. 0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ABDONEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	Ũ	0	C	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	C	0	0	0	C	0	0	0	0

STUDY NO.: 0278

ANIMAL: RAT F344/DuCrj
REPORT TYPE: A1 104

SEX: NALE

Clinical sign	Group Name	Admini	stration W	leek-day _											
		28-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
NTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	. 0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	. 0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I.PERI MOUTH	Control	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	.0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	Û	0	C	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0278 ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name		stration We	ek-day _											
		42-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
NTERNAL MASS	Control	0	0	0	0	٥	٥	0	0	0	٨	٥	٥	0	۸
INTERNAL NASS		-		-		0	0	0	•	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	- 0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	. 0
.PERI MOUTH	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.EAR	Control	0	0	0	0	0	- 0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I.PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0 .	0	0	0	Ö	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ô	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	ō	0
I.BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	Ō	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	Ö	Ō	0	ő	0
I. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	1	i	1	1	1	1	1	1	1
	2000 ppm	0	0	0	0	0	0	3	3	3	1	2	2	2	2
	4000 ppm	0	0	0	0	0	Č	0	0	1	1	1	0	0	0

STUDY NO. : 0278 ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

PAGE: 21 SEX : MALE

linical sign	Group Name		stration W												
		56-7	57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
NTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	٨	0	^
MIERNAL MASS		0	0	-	0	0	. 0	0	0	0	0		0	-	0
	1000 ppm 2000 ppm	0	0	0		0	0	0			0	0	0	0	0
	4000 ppm	0	0	0	0 0	0	0	0	0	0	0	0	0	0	0 0
.NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	Ō	o O	0	0	0	0
	4000 ppm	0	Ö	Ö	Ö	ŏ	0	0	Ö	0	0	0	0	ō	0
PERI MOUTH	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
.EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	Ö	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	. 0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	1	1	1	1	1	1
. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	1	1	1	1
	1000 ppm	1	1	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	2	1	3	2	2	1	2	2	2	3	3	3	3	3
	1000 mag	0	0	0	O	0	0	0	0	0	0	0	0	1	1

STUDY NO.: 0278
ANIMAL: RAT F344/DuCrj
REPORT TYPE: A1 104

SEX : MALE

Clinical sign	Group Name		istration W												
		70-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
NTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TILIMINI, MICO	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	Ö	ő	0	ő	2	2	1	0	Ö	0	Ö	1	0	0
.NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.PERI MOUTH	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	1000 ppm	0	0	0	0	1	1	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	4000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
.EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	1	1	2	2	2	2	2	2	2	2	2	2	2	2
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I.PERI EAR	Control	0	0	0	1	1	1	1	1	1	1	1	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	2
1.BREAST	Contral	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	1	1	1	1	2	2	2	2	2	2	2	2	2	2
1. ABDOMEN	Control	1	1	1	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
	2000 ppm	3	3	3	3	3	3	3	3	3	3	. 3	3	3	4
	4000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	2	2

STUDY NO.: 0278 ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : NALE PAGE: 23

linical sign	Group Name	Admini	stration W	eek-day _											
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
NTERNAL MASS	Control	0	0	0	1	1	1	1	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.PERI MOUTH	Control	2	2	2	1	1	1	1	1	1	1	1	1	1	1
	1000 ppm	0	0	0	0	0	0	0	0	1	0	0	0	1	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	1	1	1	1	1	1	1	1	1	2	2	1	1	1
.EAR	Control	0	0	0	0	1	1	1	i	1	1	1	1	1	1
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	. 0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	1	1	2	2	2
	2000 ppm	0	0	0	0	0	0	0	0	1	1	1	1	1	1
	4000 ppm	1	2	2	2	2	2	2	2	2	2	2	2	2	1
.BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	1	1	1	1	1	1	1	2	2	2	2
	2000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	2
	4000 ppm	2	3	3	3	4	5	5	5	5	5	5	5	5	7
. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	1000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	2	2
	2000 ppm	4	5	5	6	Я	6	6	6	6	6	6	6	6	6
	1000 ppm	2	2	3	3	4	5	6	6	6	3	6	5	5	5

(HAN190)

STUDY NO.: 0278

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104 CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : MALE

linical sign	Group Name	Admin	istration	Week-day						
		98-7	99-7	100-7	101-7	102-7	103-7	104-7		
		1	1	1	1	1	1	1		
INTERNAL MASS	Control	0	0	0	1	1	1	0		
	1000 ppm	0	0	0	0	0	0	0		
	2000 ppm	1	1	1	2	2	2	2		
	4000 ppm	1	1	1	0	1	1	1		
. NOSE	Control	0	0	0	0	0	0	0		
	1000 ppm	0	0	0	0	0	0	0		
	2000 ppm	0	0	0	0	1	1	1		
	4000 ppm	0	0	0	0	0	0	0		
PERI MOUTH	Cantral	1	1	1	1	- 0	0	0		
	1000 ppm	0	0	0	0	0	0	0		
	2000 ppm	1	1	0	0	0	0	0		
	4000 ppm	1	1	1	1	1	1	1		
EAR	Control	1	1	1	1	1	1	1		
	1000 ppm	0	0	0	0	0	0	0		
	2000 ppm	2	2	2	2	2	2	2		
	4000 ppm	0	0	0	0	0	0	0		
PERI EAR	Control	0	0	0	0	0	0	0		
	1000 ppm	0	0	0	0	0	0	0		
	2000 ppm	0	0	0	0	0	0	0		
	4000 ppm	0	0	0	0	0	0	0		
NECK	Control	0	0	0	1	1	1	1		
	1000 ppm	2	2	2	3	3	3	3		
	2000 ppm	0	0	0	0	0	0	0		
	4000 ppm	1	1	1	1	1	1	1		
BREAST	Control	0	0	0	0	0	0	0		
	1000 ppm	2	2	2	2	2	3	3		
	2000 ppm	2	3	3	3	4	4	3		
	4000 ppm	5	6	6	6	6	6	6		
ABDOMEN	Control	1	1	1	1	1	1	0		
	1000 ppm	3	3	3	3	4	4	5		
	2000 ppm	5	5	5	5	5	5	4		
	4000 ppm	5	5	5	6	6	6	6		

STUDY NO.: 0278

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

SEX : MALE

linical sign	Group Name	Admini:	stration We	eek-day											
		1-1	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
ANTEDIOD DODOUN	Control 1	0	•	•	•	•		•							
.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	. 0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0 .	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.HINDLIMB	Contral	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
.TAIL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	Ô	0	0	. 0	0
	2000 ppm	0	0	0	0	0	0	0	Ō	0	Ö	Ö	0	Ö	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ö	0
NEN I A	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	Ō	0	Ŏ	Õ	Ö	0
	2000 ppm	0	0	0	0	0	0	0	0	0	Ö	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	Ő	ŏ	0	0	0	Ö
AUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	Ŏ	Õ	0	Ö	0	0
	2000 ppm	0	0	Ö	Ö	Ŏ	0	0	0	Ô	0	0	0	0	0
	4000 ppm	0	0	0	Ŏ	Ö	Ö	Ö	Ö	0	0	0	0	0	0
SCITES	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	C	0	0	0	0		
	4000 ppm	0	0	0	0	0	0	0	0	0	C	0	U	0	0

STUDY NO.: 0278

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admini	Administration Week-day												
		14-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
												· · · ·			
I.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	.0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	Ō	Ö	0
I.POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	Ō	Ö	Ö	0	Ö	0	0
M.HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	Ö	0	Ö	0
	2000 ppm	0	0	0	0	0	0	0	Ö	Ŏ	ő	ő	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	Ô	0	0	0
	2000 ppm	0	0	0	0	0	0	0	Ö	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	Ö	Ö	Ö	Ö	Ö	0	0	0
M.TAIL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	Ō	Ö	Ö
ANENIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	Ō	Ö	0	ő	Ŏ	0	0	0
	2000 ppm	0	0	0	0	0	0	0	Ö	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	Ö	. 0	Ö	Ö	0	0	0	0
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	Ō	0	Ô	0	0	0	0
	2000 ppm	0	0	0	0	0	Ö	Ö	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	Ō	o	0	0	Ö	0	0	0
SCITES	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	Ō	Ö	ŏ	Ö	Ŏ	0	0	0	0	0	0
	2000 ppm	C	Ö	0	0	0	õ	Ö	Ö	0	0	0	0	0	0
	4000 ppm	0	0	0	Ö	0	0	0	0	0	G.	0	0	0	0

STUDY NO. : 0278

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : NALE

Clinical sign	Group Name	Admini	Administration Week-day												
		28-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
I.ANTERIOR, DORSUM	Control	0	0	0	0	0	0	0	0	0	0	٨	٥	•	
······································	1000 ppm	0	0	0	0	0	0	0	0	0		0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	Ö	Ö	0	0	0	0	0	0	0	0	0	0	0
POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	Ö	0	Ô	0	0
	4000 ppm	0	0	0	0	0	0	Ö	0	Ö	ő	Ö	ŏ	Ö	0
M.HINDLINB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0.	0	0	0	0	0	0	0	0	0	Ö	0
	2000 ppm	0	0	0	0	0	0	Ō	Ö	Ô	Ő	Ö	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	Ō	Ŏ	Ö	Ö	Ö
LGENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.TAIL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEM I A	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	Ö	Ö
AUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
	2000 ppm	0	0	0	0	0	0	0	0	0	0	Ö	Ö	Ö	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	Ō	0	Ö
SCITES	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	Ô	0	0	Ö	ő
	2000 ppm	0	0	0	0	0	0	0	O	0	0	Ō	0	0	ŏ
	4000 ppm	0	0	0	0	0	0	0	0	0	C	0	0	0	0

STUDY NO. : 0278 ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Group Name Administration Week-day																
		42-7	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			
		1	1	1	1	1	1	1	1	1	1	1	1	1	1			
William Dobcin	Control				•		•	•	•					_				
.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0		0			
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0		0			
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0		0			
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
.POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	2000 ppm	0	0	0	0	0	0	0	. 0	0	0	0	0	0	0			
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
.HINDLIMB	Contral	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0		•	Ö			
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	0	0			
.TAIL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	2000 ppm	0	0	0	0	0	0	0	0	0	0	Ô	0	-	0			
	4000 ppm	0	0	0	0	0	0	0	0	0	0	Ô	0	Ŏ	0			
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0		ő			
	4000 ppm	0	0	0	0	0	0	0	0	0	Ö	Ö	0		0			
AUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	1000 ppm	0	0	0	0	0	0	0	0	Ö	0	0	0	•	ő			
	2000 ppm	0	0	Ö	0	0	Ŏ	Ŏ	ő	ŏ	Ö	0	0		0			
	4000 ppm	0	0	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Ö	0		0			
SCITES	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	. 0			
	1000 ppm	0	0	0	0	0	0	Ö	0	Ö	Ŏ	Ö	ő	•	Ő			
	2000 ppm	. 0	0	0	Ö	ŏ	Ö	0	Ö	0	ñ	Ú	0		0			
	4000 ppm	0	0	0	Õ	Õ	Č	0	Ö	Ö	Ö	0	0	0	0			

STUDY NO. : 0278
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admini	Administration Week-day												
: =: = ::		56-7	57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7
		1	1	1	1	1	1	.1	1	1	1	1	1	1	1
M.ANTERIOR.DORSUM	Contral	0	0	0	0	0	0	0	0	0	0	0	٥	0	0
n. ANTERTOR. DORSON	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	-
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	. 0	0	0	0	0	0
	1000 PPIII	·	Ů	v	v	v	v	·	v	v	v	v	v	v	v
M.POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 mag	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	
	lidd oons	V	U	U	U	U	U	v	U	U	U	U	U	U	0
M.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.TAIL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	o o	Õ	0	0	Ő	Ö	0	0	0	0	0	0	0	0
	2000 ppm	Ö	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0		0
	4000 PAII	V	V	U	U	v	U	U	U	U	U	U	U	0	U
ANEMI A	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0 -	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
DHONDIOL	1000 ppm	0	0	0	0	0		0				0	•		0
		0	0	0	-		0		0	0	0	Ū	0	0	0
	2000 ppm		0		0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	U	0	0	0	0	0	0	0	0	0	0	0	0
ASCITES	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	ů.

STUDY NO. : 0278

ANIMAL : RAT F344/DuCrj

REPORT TYPE: A1 104

SEX: MALE

Clinical sign	Group Name	Admini	istration W	leek-day _											
		70-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	0	0	٥	0	٥	0
I. ANTENTON . DONSON	1000 ppm	0								-	0	0	-	0	0
			0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0 .	0	0
1.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.TAIL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	1	1	1	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ō	Õ
ANEMI A	Control	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	1000 ppm	0	0	0	0	0	0	Õ	0	Ŏ	Ô	Ö	0	0	0
	2000 ppm	0	0	0	0	0	0	Ō	Ö	Ö	0	0	0	0	0
	4000 ppm	0	0	1	0	0	Ŏ	0	ő	0	ő	Ö	ő	Ö	0
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ö	0
	2000 mag	0	0	0	0	0	0	0	0	0	ő	0	Ô	0	0
	4000 ppm	0	0	0	0	Ö	Ö	0	ő	0	Ö	0	ő	0	0
ASCITES	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	Ö	Ö	0	0	0	ő	0
	2000 ppm	0	0	Ö	0	0	Ü	0	Ö	0	0	0	0	Ö	0
	4000 ppm	0	0	0	0	0	0	0	0	Õ	Ċ	0	0	0	0

STUDY NO. : 0278 CLINICAL OBSERVATION (SUMMARY) ANIMAL : RAT F344/DuCrj ALL ANIMALS

REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admini	stration W	leek-day											
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
															-
M.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	1	2	2	2	2	2	2	2
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	1	1	1	1	1	1	1	1	1	1	1	1
POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	1	1	2	2	2	2	2	2	2	2	2
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	2	2	2	2	2	2	2	2	2	2	2
M.HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	Ö	o O	Ŏ	0	Ö	0	0	0	0	0	0	0
	2000 ppm	0	Ö	0	0	0	1	1	1	1	1	1	1	1	1
	4000 ppm	0	Ö	0	Ö	Ö	0	0	0	0	0	0	0	0	1
M.GENITALIA	Control	0	0	0	0	0	0	0	^	0	0	^			•
ODNI INDIA	1000 ppm	0	0	0					0	. 0	•	0	0	0	0
	2000 ppm	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
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.TAIL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	1	1	1	1	1	1	1	1	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	. 0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	Ö	Ŏ	Ô	Ŏ	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	Õ	Ö	0	0	1
	4000 ppm	0	0	0	0	0	0	Ō	0	0	0	ő	Ö	1	1
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	Ô	Ō	Ö	Ŏ	Ŏ	Ö	Ö	0	0	0	0	0	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	•
	4000 ppm	ő	ő	0	0	0	0	0	0	0	0	0	0	0	0
ASCITES	Control	0	0	0	0	0	0	0	^	Λ	^	^	^	^	2
	1000 ppm	0	0	0	0	0		1	0	0	0	0	0	0	0
	2000 ppm	0	0	0			1	_	1	1	1	1	1	1	0
		-	0		0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	U	0	U	0	0	0	0	0	0	0	0	0	0

STUDY NO.: 0278 ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admini	istration	Week-day					
-		98-7	99-7	100-7	101-7	102-7	103-7	104-7	
		1	1	1	1	1	1	1	
M.ANTERIOR.DORSUM	Contral	2	2	2	2	2	2	2	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	1	1	1	1	1	1	1	
	4000 ppm	1	2	2	3	2	2	2	
M.POSTERIOR DORSUM	Contral	0	0	0	0	0	0	0	
	1000 ppm	2	3	3	2	2	2	2	
	2000 ppm	0	0	0	0	0	0	0	
	4000 ppm	2	2	2	2	2	2	1	
M.HINDLIMB	Control	0	0	1	1	1	1	1	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	1	1	1	0	0	0	0	
	4000 ppm	1	1	0	0	0	0	0	
M.GENITALIA	Control	0	0	0	0	0	0	0	
	1000 ppm	1	1	1	1	1	1	1	
	2000 ppm	0	0	0	0	0	0	0	
	4000 ppm	0	0	0	0 .	0	0	0	
M.TAIL	Cantrol	0	0	0	0	0	0	0	
	1000 ppm	1	1	1	1	1	1	1	
	2000 ppm	0	0	0	Ō	0	Ô	0	
	4000 ppm	0	0	0	0	0	0	Ö	
ANEMIA	Control	0	0	0	0	0	0	1	
	1000 ppm	0	0	0	0	Ö	0	ō	
	2000 ppm	1	1	2	1	2	i	0	
	4000 ppm	i	1	1	0	0	1	1	
JAUNDISE	Control	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	. 0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	
	4000 ppm	0	0	0	0	0	0	0	
		v	v	v	v	v	v	V	
ASCITES	Control	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	
	4000 ppm	0	0	0	0	0	0	0	

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : MALE

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Clinical sign	Group Name	Adminis	stration W	eek-day											
		1-1	1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-1
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
RREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
UBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(

(HAN190)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : MALE

PAGE: 34

Clinical sign	Group Name	Admini	istration W	leek-day											
		14-7	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-
		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	٥
	1000 ppm	o o	Ô	Ö	Ô	ő	0	0	0	0	0	. 0	0	0	0
	2000 ppm	Ô	0	0	0	0	0	0	0	0	0	0	n	0	0
	4000 ppm	0	0	0	0	0	Ö	ő	0	Ö	0	Ö	Ö	0	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0 .	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BRADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
UBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : MALE

PAGE: 35

Clinical sign	Group Name	Admini	stration W	eek-day											
		28-7	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-
		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	٥	0	0	0	^
MILOGODAN DALATITING	1000 ppm	0	0	0	0	0	0	0			0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	ĺ
		0	0	0	•	0		0	0	-	0	0	0	0	U
	4000 ppm	0	V	U	0	0	0	0	0	0	U	0	0	U	(
BNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
RADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
UBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(

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CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

ANIMAL : RAT F344/DuCrj REPORT TYPE : AI 104

SEX : MALE

PAGE: 36

Clinical sign	Group Name	Admini	stration W	eek-day											
		42-7	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
		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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	. 0	0	0	0	0	0
BNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : MALE PAGE: 37

Clinical sign	Group Name	Admini	stration W	eek-day _											
		56-7	57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
IRREGULAR BREATHING	Control	0	0	0	n	0	0	0	0	0	0	0	0	٥	٥
THE COUNTY DIENTIFIE	1000 ppm	0	0	0	n	0	0	0	0	0	0	0	٥	٥	0
	2000 ppm	0	0	0	0	0	0	0	0	n	0	. 0	0	0	0
	4000 ppm	ő	Ö	0	ő	0	0	0	0	Ö	Ö	0	0	Ö	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0 .	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Contral	. 0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : MALE

PAGE: 38

Stinical sign	Group Name	Admini	stration W	eek-day											
		70-7	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-
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
IDDECULAD DEFATILING	Cantan	٥	٥			۰	٥		•		•	•		•	
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	Û	U	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	Ü	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	- 0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BRADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	Õ	o o	Ö	0	ő	0	0

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ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : MALE

PAGE: 39

Clinical sign	Group Name	Admin	istration W	leek-day _											
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
IRREGULAR BREATHING	Control	0	٥	0	0	1	0	0	0	0	0	0	0	0	0
THE DOLLAR DECEMBER	1000 ppm	0	٥	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	TOOO PHIII	V	V	v	V	V	V	V	V	V	V	V	V	V	U
ABNORMAL RESPIRATION	Control	0	0	0	0	1	0	0	0	0	0	0	0	0	. 0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BRADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	1	1	0	0	0	0	0	0	0	0	C
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	. 0	0	0	0	0	0	0	0	0

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ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

PAGE: 40

Clinical sign	Group Name	Admini	stration	Week-day				
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
		1	1	1	1	1	1	1
IRREGULAR BREATHING	Control	0	0	0	0	0	1	0
	1000 ppm	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	2	0
	4000 ppm	0	0	0	0	0	0	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	1	0
	1000 ppm	0	0	0	0	0	0	0
	2000 ppm	0	0	0	1	0	2	1
	4000 ppm	1	0	0	0	0	0	0
BRADYPNEA	Control	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0
	2000 ppm	0	0	0	1	0	2	1
	4000 ppm	1	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	2	0
	1000 ppm	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	2	Õ
	4000 ppm	1	0	0	0	0	0	Ŏ

(HAN190)

APPENDIX A 2

CLINICAL OBSERVATION: SUMMARY, RAT: FEMALE

(2-YEAR STUDY)

STUDY NO.: 0278 ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-day											
		1-1	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	Control	0	0	0	0	0	0	0	0	0	0	٥	0	۰	
71.MTH	1000 ppm	0	0	0		-		•	0	0	0	0	0	0	0
	2000 ppm	-	-	-	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	U	U	U	U	0	0	0	0	0	0	0	0	0	. 0
ORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ō
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ō	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	Ö	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	
	4000 ppm	Ö	0	0	0	0	0	0	0	0	0	0	0		0
	4000 ppiii	V	V	V	V	v	v	U	V	U	U	U	U	0	0
ARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
VASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	Ō	0	0	Ö	0	0	0	0	0
	2000 ppm	0	0	0	0	0	Ŏ	0	Ö	ő	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	Ō	Ö	0	ŏ	0	0	0
ROG BELLY	Contral	0	•	٥					•						
NOO DEBUI	Control 1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	-	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	U	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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	Ō	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ö	Ö
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	Ö	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	Ö	0	0	0	0	0	0	0	0	G	0	-	
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Tood Phili	v	•	`'	V	**	v	V	v	U	V	U	υ	U	0

STUDY NO. : 0278
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-day _											
		14-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
EATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ō
	4000 ppm	0	0	0	0	0	0	0	0	Ö	Ö	Ö	0	0	0
OCOMOTOR NOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	Ō	0	0	Ö	0	0	Ŏ	0	0	0	o o
	4000 ppm	0	0	0	0	0	0	0	0	0	0	ő	0	0	0
ARALYTIC GAIT	Contral	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	Ö	0	0	Ŏ	Õ	Ö
	4000 ppm	0	0	0	0	Ö	0	0	0	Ö	0	ő	0	0	Ö
ASTING	Contral	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	G	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO.: 0278 ANIMAL : RAT F344/DuCrj

REPORT TYPE: A1 104

SEX : FEMALE

linical sign	Group Name	Admini	stration W	eek-day _											
		28-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
ЕАТН	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	ő	ŏ	ő	Ö	Ö	Ö	ő	Ö	0	0	0	0	0
DRIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OCOMOTOR MOVEMENT DECR	Control	0	0	0 .	0	0	0	0	0	0	0	0	0	0	0
NOTOR HOVERENT DECK	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	.0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	()	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ASTING	Cantrol	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
XOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	C	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name		stration W												
		42-7 1	43-7 1	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7
		1	<u> </u>	1	1	1	1	1	1	1	1	1	1	1	1
РЕАТИ	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ŏ
	2000 ppm	0	0	0	0	0	0	0	0	Ö	0	0	0	0	Ŏ
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	. 0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	, 0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	, 0
MASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	Contral	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ö	Ö
	2000 ppm	0	0	0	0	0	0	0	0	0	0	G	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO.: 0278 CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : FEMALE

linical sign	Group Name		istration W											-	
		56-7	57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
TATII	Control	0	0	0	•	^	^	2	•	•	•				
MIII.	1000 ppm			0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	U	U	0	0	0	0	0	0	1	2	2	2	2
DRIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
DOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1900 ppm	0	0	0	0	Ö	0	0	Ö	Ö	Ö	Ő	0	0	0
	2000 ppm	0	0	0	0	0	Ö	Ö	Ö	0	0	0	0	0	-
	4000 ppm	Ŏ	Ö	Ö	ő	1	Ö	0	0	0	0	0	0	0	0
ARALYTIC GAIT	C11	•	•	•	•		_								
ARABITO GATT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ROG BELLY	Control	0	0	0	0	0	0	0	0	. 0	0	0	0	0	0
-	1000 ppm	Õ	0	Ö	0	0 0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	Ö	0	0	0		-	-	•	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ALLEN DEDL GENERALL							-	•	v	·	v	•	v		V
DILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	maa 000S	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	ő
COPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	ŏ	Ö	ő	0	Ö	ő	ő	0	0	0	0	0	0
	2000 ppm	Ö	0	0	0	0	0	0	0	0	0	0	0		
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : AI 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	leek-day _											
		70-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	Control	0	1	1	1	1	1	1	1	1	1	1	1	1	1
J	1000 ppm	0	Ô	0	î	1	1	1	1	1	1	1	1	1	2
	2000 ppm	0	0	0	0	0	0 .	0	0	0	0 -	0	0	0	2
	4000 ppm	2	2	2	2	2	2	2	3	4	4	4	4	4	4
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	1	i	1
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	ő
	4000 ppm	. 1	1	1	1	1	1	2	2	2	2	2	2	2	2
LOCONOTOR NOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
PARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	1	1	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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	1	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	C	Û	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	C	0	0	0	0	0	0	0	0	0

STUDY NO. : 0278
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 104

Group Name

4000 ppm

Control

1000 ppm

2000 ppm

1000 ppm

0

0

0

0

0

SEX : FEMALE
Clinical sign

		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	Control	1	1	1	1	1	2	2	2	2	2	2	2	2	2
	1000 ppm	2	2	2	2	2	2	2	4	4	4	4	4	4	4
	2000 ppm	0	0	0	0	0	0	0	0	1	1	1	3	3	3
	4000 ppm	4	4	6	6	7	7	7	7	7	7	7	7	8	9
MORIBUND SACRIFICE	Control	1	1	1	2	2	2	2	2	2	2	2	2	2	2
	1000 ppm	0	0	0	0	0	0	0	0	0	1	1	1	2	3
•	2000 ppm	1	1	2	2	2	2	2	2	2	2	2	2	2	2
	4000 ppm	2	2	2	2	4	4	4	4	4	4	4	4	4	5
LOCOHOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	2000 ppm	1	0	0	0	0	0	0	0	0	0	0	0	Ö	0
	4000 ppm	1	0	0	0	1	0	0	0	0	0	0	0	Ö	Ö
PARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	1	1	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ō
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	. 0	0	Ō
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	Ö	0	Ö	ŏ	0
	4000 ppm	0	0	0	0	1	1	0	0	0	0	0	Ö	0	ő
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	ī	1	0	Ö
	2000 ppm	0	0	0	0	0	0	0	0	0	Õ	0	0	0	Ö
	4000	^	^	•	•		-						•	v	V

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Administration Week-day _____

EXOPHTHALMOS

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STUDY NO. : 0278 CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : FEMALE PAGE: 48

Clinical sign	Group Name	Admini	stration	Week-day				
	,	98-7	99-7	100-7	101-7	102-7	103-7	104-7
		1	1	1	1	1	1	1
DEATH	Control	2	2	2	2	2	2	2
	1000 ppm	4	4	4	4	5	6	6
	2000 ppm	3	4	4	5	5	5	5
	4000 ppm	9	9	10	11	13	13	13
MORIBUND SACRIFICE	Control	2	3	3	3	3	3	3
	1000 ppm	4	4	4	4	4	4	4
	2000 ppm	2	2	2	2	2	2	2
	4000 ppm	5	5	5	5	6	6	7
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0
	1000 ppm	1	Õ	0	0	0	0	0
	2000 ppm	Ö	Ö	0	Ö	0	0	ŏ
	4000 ppm	0	0	ő	Ö	1	0	1
DIDILUTIC CLIT	G	^	•	۰			•	•
PARALYTIC GAIT	Control	0	0	0	0	0	0	0
	1000 ppm	0	0	0	1	1	1	1
	2000 ppm	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0
	1000 ppm	1	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0
FROG BELLY	Control	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	1	0	0
	2000 ppm	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	1	0	0
	2000 ppm	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0
	4000 ppili	v	U	U	U	U	U	U
EXOPHTHALMOS	Control	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0
	2000 ppm	0	0	0	û	0	1	1

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-day _											
		1-1	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
			1	1	1	1	1	1	1	1	1	1	1	1	1
YE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
are or norm	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	o	0	0	0	0	Ō	0	Ŏ	Ö	0	Ö	0
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	.0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I.PERI MOUTH	Contral	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	G	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	C	0	0	0	0

STUDY NO. : 0278
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 104

SEX: FEMALE

Clinical sign	Group Name	Admini	stration W	eek-day											
		14-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
YE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	1	1	1	1	1	1	1	1	1	2	2	2	2
	2000 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	1	1	1	1	1	1	1	1	1	2	2	2	2
	2000 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
XTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	Ô	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
	4000 ppm	0	0	0	0	0	0	Ó	0	0	Ö	0	Ö	0	0
NTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	Ö	0	ŏ	ő	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	Ŏ	0	0	0	0	0
	2000 ppm	0	0	0	Ö	Ö	Ö	0	0	0	0	0	0	0	0
	4000 ppm	0	Ō	Ö	Ö	Ö	0	0	Ö	0	0	0	0	0	0
.PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	Ö	0	0	0	0	0
	2000 ppm	0	0	0	Ō	0	0	0	Ŏ	Ö	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	Ö	Ö	0	Ö	Ö	Ö	Ö	0
. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	Ö	Ō	Ö	Ŏ	0	0	0	0
	2000 ppm	0	0	0	0	Ō	0	Ċ	ő	Ö	0	Ö	0	0	0
	4000 ppm	0	0	0	0	Ô	0	0	0	0	0	0	0	0	0

STUDY NO. : 0278 CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	leek−day											
		28-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
ant objectan		•	•	•						_					
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	2	2	3	3	3	3	3	3	3	3	3	3	3	3
	2000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	4000 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
	1000 ppm	2	2	3	3	3	3	3	3	3	3	3	3	3	3
	2000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	Ö	0	0	0	0 .	0	0	0	0	0	0
EXTERNAL MASS	Contral	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Õ
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0.	0	0	0	0	0	Ő
	2000 ppm	0	0	0	0	0	0	0	0	0	Ô	Ö	o o	0	Ö
	4000 ppm	0	0	0	0	0	0	0	0	Ö	0	0	0	0	ŏ
M.EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	Ō	0	0	Ö	ŏ	Ö	Ö	0	0	0	0	0	0	0
	2000 ppm	Ö	Ō	0	ŏ	0	Ö	0	0	0	0 *	0	0	0	0
	4000 ppm	0	0	0	Ö	0	0	Ö	Ö	Ö	Ö	0	0	0	0
I.PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	Ö	0	0	Ŏ	0	ő	0	0	0	0	0	0	0	0
	2000 ppm	0	Ö	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	Ő	0	Ö	ő	Ö	Ö	0	Ö	0	0	0	0	0	0
I.NECK	Control	0	0	0	0	. 0	0	0	0	0	0	0	0	0	0
	1000 ppm	Ö	Ŏ	ő	Ő	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	Ö	0	0	0	0	0	0	0	0	0	0	0	-
	4000 ppm	Ö	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO.: 0278 ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : FEMALE PAGE: 52

Clinical sign	Group Name		stration W												
		42-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
					<u></u>										
YE OPACITY	Contral	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	1000 ppm	3	3	3	3	3	3	3	3	3	4	4	4	4	4
	2000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	i
	4000 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	1
	1000 ppm	3	3	3	3	3	3	3	3	3	4	4	4	4	4
	2000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	4000 ppm	0	0	Ō	0	ō	Ô	ō	Ô	0	Ô	0	0	0	0
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	Ö	0	0	0	0	Ö
	2000 ppm	0	0	0	0	0	0	0	Ö	Ŏ	0	Ŏ	Ö	0	ő
	4000 ppm	0	0	0	0	0	0	0	0	0	Ö	0	0	0	Ö
XTERNAL NASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	1	1	1	Ī	1
	2000 ppm	0	0	0	0	0	0	0	0	Ŏ	0	0	Ô	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	0	Ö
NTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ō
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	1 .
1.EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	0	0
I.PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	Ŏ	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	Ö	Ö	Ö	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	0	0
1. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	Ö	Ŏ	Ŏ	0	Ö
	2000 ppm	0	0	0	0	0	0	0	0	0	. 0	Ŏ	0	Ö	Ö
	4000 ppm	0	0	0	0	0	0	0	0	Ŏ	0	Ö	0	. 0	0

STUDY NO. : 0278
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 104

SEX: FEMALE

Clinical sign	Group Name	Admini:	stration W	leek-day											
		56-7	57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
EYE OPACITY	Cambinal	1	,	•	•										
SIE OPACITY	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	1000 ppm	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	2000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	1000 ppm	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	2000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	1	1	1	1	1	1	1	1	1	1 .	1	1	1	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	õ	0	0
	4000 ppm	0	0	1	2	2	2	2	2	2	2	2	2	2	2
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ō
	4000 ppm	1	1	1	1	1	1	1	1	1	0	0	0	Ô	Ö
M.EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	Ö	Õ	0	Ö
	4000 ppm	0	0	0	0	0	0	0	Ō	0	ō	Ö	0	ŏ	Ö
1.PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	Ŏ	0	0	0	Ô	0	0	0	0
	2000 ppm	0	0	0	Ŏ	Ő	Ő	0	0	0	0	0	0	0	0
	4000 ppm	0	ő	ő	1	1	1	1	1	1	1	1	1	1	1
M. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	Ō	0	Ö	0	0	0	0	Ö	0	0	0	0	0	0
	2000 ppm	Ö	Ô	Ö	ŏ	0	0	0	G	0	0	0	0	0	0
	4000 ppm	Ö	0	0	0	0	0	0	0	0	0	0	0	0	0
	TOOU PPILI	v	v	9	v	v	v	v	v	v	v	V	V	U	V

STUDY NO. : 0278

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-day											
		70-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
YE OPACITY	Control	i													
HE OFACITY	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	1000 ppm	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	2000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATARACT	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	1000 ppm	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	2000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORNEAL OPACITY	Control	0	0	0	0	0	0	Ō	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ö	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	. 0
KTERNAL MASS	Control	0	0	0	0	0	0	0	1	1	1	1	1	2	2
	1000 ppm	1	1	1	1	1	1	1	. 1	1	1	Ī	î	2	1
	2000 ppm	0	0	0	0	0	0	0	ō	Ô	Ô	Ô	0	0	Ô
	4000 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
NTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	Ö	0	ő	0	0	0
	2000 ppm	0	0	0	0	0	0	0	Ŏ	Ö	1	1	2	1	1
	4000 ppm	0	0	0	0	0	Ö	0	0	Ö	ó	0	2	2	2
.EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	Ô	Ō	Ö	Ö	ő	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	Ô	0	Ö	Ő	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	Ö	Ö	Ö	Ö	Ö	0	0	0	0	0	0
PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	ő	ő	0	0	0	0	0	0	0	0
	2000 ppm	Õ	0	0	Ö	Ö	0	0	0	0	0	0	0	0	
	4000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	0 1
NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	Ö	0	Õ	0	0	0	0	0	0	0	0	0	0
	2000 ppm	ő	0	0	0	0	0	0	0	0	0	-	-	0	0
	4000 ppm	0	0	0	0	0	0	0	0		-	0	0	0	0
	TOOU PAIN	v	v	V	v	U	U	U	U	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	leek-day											
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
														·	
EYE OPACITY	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	1000 ppm	4	4	5	5	5	5	5	5	5	5	5	5	4	3
	2000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	4000 ppm	0	0	0	0	0	0	0	0	0	0	Ô	0	0	0
CATARACT	Control	1	1	1	1	1	1	1	1	1	t	1	I	1	1
	1000 ppm	4	4	5	5	5	5	5	5	5	5	5	5	4	3
	2000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	4000 ppm	0	0	0	0	ō	Ô	ō	0	Ô	0	0	0	0	ó
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	Ŏ	0	0	0	0
	2000 ppm	0	0	Ö	0	ő	0	0	0	0	0	0	0	0	0
	4000 ppm	Ō	0	Ö	0	Ö	Ŏ	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	3	4	4	4	4	4	4	4	4	4	4	4	5	6
	1000 ppm	1	1	1	2	î	1	1	1	1	1	1	1	2	2
	2000 ppm	ō	0	î	1	1	î	1	1	1	1	1	2		
	4000 ppm	2	2	2	2	2	2	2	2	3	3	3	3	2 3	3 5
INTERNAL MASS	Control	0	0	0	0	0	0	0	0						
INTERIOR IMOS	1000 ppm	0	-		-	0	0	0	0	0	0	0	0	0	0
		-	0	0	0	0	0	0	0	0	0	1	1	1	1
	2000 ppm	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	2	3	3	3	1	0	0	0	1	1	1	1	1	1
M.EYE	Control	0	1	1	1	1	1	1	1	1	1	1	1	1	1 .
	1000 ppm	0	0	0	0	0	0	0	Ō	0	0	Ô	0	Ô	0
	2000 ppm	0	0	0	0	0	0	Ö	0	Ŏ	Ő	Ŏ	0	0	0
	4000 ppm	0	0	0	0	0	0	0	ŏ	Ö	Ö	0	ő	0	1
M.PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	1000 ppm	0	0	Ŏ	ő	ő	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	Ö	0	0	0	0	0	0	0	0	=	-
	4000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	0 1	0 1
M. NECK	Control	1	1	1	0	0	0	0	0	0	0	0	0	0	Λ
**	1000 ppm	Ô	Ô	0	Ŏ	0	0	0	0	0	0	0	0	0	0
	2000 ppm	Ö	0	Ö	0	Ö	ō	0	0	0	0	•	•	-	0
	4000 ppm	ņ	0	0	0	0	0	0	C			0	0	0	1
	lildd bost.	¥	U	U	v	V	U	v	Ü	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : FEMALE

	Group Name	ACHITITI	stration	week-day _					
		98-7	99-7	100-7	101-7	102-7	103-7	104-7	
		1	1	1	1	1	1	1	
EYE OPACITY	Control	1	1	1	1	1	1	1	
	1000 ppm	3	3	3	3	3	3	3	
	2000 ppm	1	1	1	1	1	2	2	
	4000 ppm	0	0	0	0	0	0	0	
CATARACT	Control	1	1	1	1	1	1	1	
	1000 ppm	3	3	3	3	3	3	3	
	2000 ppm	1	1	1	1	1	1	1	
	4000 ppm	0	0	0	0	0	0	0	
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	1	1	
	4000 ppm	0	0	0	0	0	0	0	
EXTERNAL MASS	Control	5	6	6	6	6	8	9	
	1000 ppm	2	2	3	4	5	6	6	
	2000 ppm	3	8	8	8	8	8	8	
	4000 ppm	5	8	7	9	10	10	10	
INTERNAL MASS	Control	0	0	0	0	0	0	0	
	1000 ppm	1	1	1	1	1	0	0	
	2000 ppm	0	0	0	0	0	0	0	
	4000 ppm	1	1	0	1	1	0	0	
M.EYE	Control	1	1	1	1	1	1	1	
	1000 ppm	0	0	0	0	0	0	ō	
	2000 ppm	0	0	0	0	0	0	0	
	4000 ppm	1	ĺ	1	1	1	1	1	
M.PERI MOUTH	Control	0	0	0	0	0	0	0	
	1000 ppm	Ö	0	0	Ŏ	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	
	4000 ppm	í	1	0	0	0	0	0	
		•		•	•	v	V	V	
M.NECK	Control	0	0	0	0	0	1	1	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	1	1	1	1	1	1	1	
	4000 ppm	0	0	0	0	0	0	0	

ANIMAL : RAT F344/DuCrj

REPORT TYPE: A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-day											·
		1-1	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M.FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	٥	0	٥	0
at out in	1000 ppm	0	0	0	0	0	0	0	-			0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000	v	v	v	v	V	V	v	V	V	v	V	V	V	V
N.BREAST	Cantrol	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	Ŏ	Ö	0	0	ő	0	0	0	0	0	0	0	0	0
	2000 ppm	Ö	0	Ö	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppiii	U	V	V	V	V	V	V	V	V	V	U	U	U	U
M.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	Ō	Ö	ŏ	Ö	Ö	ő	0	Ô	0	0	0	0
	2000 ppm	Ö	Ö	Ö	Ö	ő	0	0	0	0	0	0	0	0	0
	4000 ppm	Ö	0	ő	0	ő	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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ANUS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	Ö	0	0	0	0	0	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	mdd oost	V	V	v	v	V	V	v	V	U	U	v	U	U	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ö	0
	2000 ppm	0	0	0	0	0	0	Û	0	0	0	0	0	0	Ö
	4000 ppm	0	0	0	0	0	0	0	C	0	0	0	0	Õ	Ö

STUDY NO.: 0278 ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : FEMALE PAGE: 58

Clinical sign	Group Name	Admini	stration W	leek-day											
		14-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
											<u> </u>				
M.FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ô
1.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	o O	0	Ö	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	. 0	0	Ö
M.HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	Ö	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ô	0
M. ANUS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	Ő	0	ő	Ö	Ö	0	Ö	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	Ö	0	ő	0
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	Ö	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0278
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-day _											
		28-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
1.FORLIMB	Control	0	0	0	0	٥	٥	٥	٥	0	٥		•	•	0
i.ronbinb	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0		-	-	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0 0	0 0	0 0
.BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
	4000 ppm	0	0	0	0	0	0	0	0	0	Ō	0	Ö	ŏ	0
. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0 .
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. ANUS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NEM I A	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	Û	0	. 0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	Ó	C	0	0	0	C	0	0	0	0

STUDY NO. : 0278 CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	leek-day											
		42-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M.FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	. 0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
N.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	. 0	0	0	0	Ô	0	0	ŏ	ő
M. ANUS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	Ô	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	ō	Ö	0	0	0	Ŏ	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	Õ	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	ů	0
	4000 ppm	0	O	0	0	0	0	0	0	0	Ô	Ŏ	0	0	0

STUDY NO. : 0278
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	leek-day _											
		56-7	57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
A CODI IND		•	۰	•	•					_					
M.FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	1	1	1	1	1	1	1	1 .	1	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	1	1	1	1	1	1	1	1	1	1	1	1
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0 -	0	0	0	0	0
	4000 ppm	0	0	0	0	0	. 0	0	0	0	0	0	0	0	0
1.ANTERIOR.DORSUM	Control	0	0	0 .	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	Ö	0	0	0	Ŏ	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	0	Ö
M.HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ö	0
	4000 ppm	0	0	0	0	0	0	0	0	0	Ö	0	Ö	Ö	0
M.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	Ŏ	Ŏ	0	Ŏ	Ö	0	0	0	0	0	0
	2000 ppm	0	0	Õ	Ŏ	0	0	0	0	0	0	0	0	0	0
	4000 ppm	Ō	0	. 0	0	ő	0	Ö	Ö	Ö	Ö	0	0	0	0
1. ANUS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	Ö	0	Õ	0	ő	Õ	0	0	0	0	0
	2000 ppm	0	Ŏ	ŏ	0	Ö	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	Ö	0	ő	ő	0	ő	0	ő	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	Ö	Ŏ	Ö	Ö	0	Ŏ	Ŏ	0	0	0	0	0	0
	2000 ppm	Č	Ö	Ő	0	0	0	0	Ü	0	0	0	0	0	0
	4000 ppm	ņ	0	0	0	0	0	0	C	0	0	0	0		
	- o o o the	•	•	•	•	V	V	V	v	v	V	v	v	0	0

STUDY NO. : 0278

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : FEMALE

linical sign	Group Name	Admini	stration W	eek-day _									·		
		70-7	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
		1	1	1	1	1	1	1	1	1	1	1 .	1	1	1
CODI IND	Control	٥	0	^	^	٥	٥	۰	•	•			•	•	
.FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.BREAST	Control	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	1000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTERIOR.DORSUN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	Ö	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	Ö	ő	Ö	0	Ö
.HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Õ	Ŏ
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ŏ	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	ő
.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	1000 ppm	0	0	0	0	0	0	0	0	0	Ö	0	Ö	Ô	Ô
	2000 ppm	0	0	0	0	0	0	0	0	0	0	Ŏ	Ö	Ő	0
	4000 ppm	0	0	0	0	0	0	0	Ō	0	Ö	Ö	0	0	0
.ANUS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	Ŏ	0	Ö	Ö	0	0	0	0	0	0
	2000 ppm	ő	0	Ö	0	0	0	0	Ö	0	0	0	0	0	0
	4000 ppm	0	0	0	0	Ö	Ö	ő	ő	ő	ő	0	ő	Ö	0
NEM I A	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	Ö	0	Ö	0	0	Ö	Ö	Ö	0	0	0	0	0	0
	2000 ppm	0	Ô	Ŏ	0	0	Ö	0	Ö	0	0	0	1	1	1
	4000 ppm	0	Ö	Õ	0	0	0	Ö	0	0	0	0	1	0	0

STUDY NO.: 0278
ANIMAL: RAT F344/DuCrj
REPORT TYPE: A1 104

SEX : FEMALE PAGE : 63

linical sign	Group Name	Admini	stration W	leek-day							•				
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
		1	1	1	1	1	1	. 1	1	1	1	1	1	1	1
.FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	٥	0
. PORLIND	1000 ppm	0	0	-				0						0	0
		0	0	0	0	0	0	_	0	0	0	0	0	0	0
	2000 ppm 4000 ppm	-	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	U	U	U	U	0	0	0	0	0	0	0	0	0
. BREAST	Control	1	1	1	2	2	2	2	2	2	2	2	2	2	2
	1000 ppm	0	0	0	1	0	0	0	0	0	0	0	0	1	1
	2000 ppm	. 0	0	0	0	0	0	0	0	0	0	0	0	0	1
	4000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	2
. ABDOMEN	Control	0	0	0	0	0	0	0	. 0	0	0	0	0	0	0
	1000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	2000 ppm	Ô	0	Ī	î	1	î	1	1	1	1	1	1	1	1
	4000 ppm	Ö	Ö	0	0	0	0	0	0	1	i	1	1	1	1
	1000 pp.iii	v	v	v	v	v	v	V	v	1	*	1	1	1	1
.ANTERIOR, DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.GENITALIA	Control	1	1	1	1	1	1	1	1	1	- 1	1	1	1	2
	1000 ppm	0	0	Ô	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. ANUS	Control	0	0	0	۸	0	0	^	^	^	0	٥	0	•	^
Conn.i	Contral 1000 ppm	0	0	-	0	0	0	0	0	0	0	0	0	0	0
		-	•	0	0	0	0	0	0	0	0	0	. 0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	. 0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NEM I A	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	Õ	Ö	1
	2000 ppm	1	0	0	0	0	0	0	0	0	0	0	0	0	Ô
	4000 ppm	0	0	0	0	1	0	0	0	0	G	0	Ŏ	1	1

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX: FENALE

Clinical sign	Group Name	Admini	stration	Week-day _				
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
		1	1	1	1	1	1	1
			· · · · · ·					· · · · · · · · · · · · · · · · · · ·
N.FORLIMB	Control	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0
	4000 phii	U	U	U	U	U	U	U
M.BREAST	Control	2	2	2	2	2	3	4
	1000 ppm	1	1	2	3	3	4	4
	2000 ppm	1	3	3	4	4	4	4
	4000 ppm	2	4	4	6	5	5	5
M. ABDONEN	Control	0	0	0	0	٥	٥	0
H. ADDOREN	1000 ppm	1		1		0	0	0
	2000 ppm	=	1	_	1	2	2	2
		1	2	2	2	2	2	2
	4000 ppm	1	2	2	2	4	4	4
M.ANTERIOR.DORSUM	Control	0	0	0	C	0	0	0
	1000 ppm	0	0	0	0	0	0	0
	2000 ppm	0	1	1	1	1	1	1
	4000 ppm	0	0	0	0	0	0	0
M.HINDLIMB	Control	0	0	0	0	0	0	0
	1000 ppm	0	Ö	Ö	ő	ő	ő	0
	2000 ppm	1	1	1	0	0	0	0
	4000 ppm	Ô	0	0	0	0	0	0
M CENTERT IA	C+1	0	0	•	•			
M.GENITALIA	Control	2	3	3	3	3	3	3
	1000 ppm	0	0	0	0	0	0	0
	2000 ppm	0	2	1	1	1	1	1
	4000 ppm	0	0	0	0	0	0	0
M.ANUS	Control	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0
	2000 ppm	0	1	1	1	1	1	1
	4000 ppm	0	ō	Ô	Ô	0	0	0
ANENIA	Contral	0	0	0	0	0	0	0
month.	1000 ppm	1	0	0	0	0	0	0
	2000 ppm	0	0	0	0			0
	4000 ppm	1	0	0	0	0 0	0	0 1
		,	v	V	v	U	v	1

ANIMAL : RAT F344/DuCrj

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

REPORT TYPE : A1 104

SEX : FEMALE

PAGE: 65

linical sign	Group Name	Adminis	stration We	eek-day											
		1-1	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
		1	1	1	1	1	1	1	1	1	1	1	1	. 1	1
AININ LOD															
AUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
REGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL RESPIRA.SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	Ö	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE: A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : FEMALE

PAGE: 66

linical sign	Group Name	Admini	stration W	eek-day _											
		14-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
UNDISE	Cantrol	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
REGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
,	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	. 0	0	0	0	0	0	0	0	0
ADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NORMAL RESPIRA.SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	o o	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO.: 0278 CLINICAL OBSERVATION (SUMMARY)
ANIMAL: RAT F344/DuCrj ALL ANIMALS

REPORT TYPE : A1 104

SEX : FEMALE PAGE : 67

Clinical sign	Group Name	Λdmini	stration W	eek-day _											
		28-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
NUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0 .	0	0	0	0	0	.0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL RESPIRA.SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ė.	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
UBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : FEMALE

PAGE: 68

linical sign	Group Name	Admini	istration W	Veek-day _											
		42-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
UNDISE	Control	0	0	٥	0	0	0	0	0	•	^	•	•	•	
ONDISE	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm 4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	V	U	U	0	0	0	0	0	0	0	0	0	0	0
RREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0 .	0	0	0	Θ	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ô	0
	2000 ppm	0	0	0	0	0	0	Ö	Ŏ	0	Ŏ	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	Ö	Ö	Ö	0
RADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	٥
	1000 ppm	0	0	0	0	0	0	0	0	0	Ô	0	ñ	0	0
	2000 ppm	0	0	0	0	Ö	0	0	Ŏ	0	0	0	٨	0	0
	4000 ppm	0	0	0	Ö	ő	0	0	0	0	0	0	0	0	0
BNORMAL RESPIRA.SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	n
	1000 ppm	0	0	Ŏ	0	0	0	0	Ö	0	0	0	٥	0	0
	2000 ppm	Ö	0	0	0	Ö	0	0	0	0	0	0	0	0	0
	4000 ppm	Ö	0	0	Ö	Ö	0	0	0	0	0	0	0	0	0
JBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	. 0	0	0
	1000 ppm	0	ő	0	ő	0	0	Ö	0	0	0	0	0	0	0
	2000 ppm	ŏ	0	Ö	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	Ő	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : FEMALE

PAGE: 69

Clinical sign	Group Name	Admini	stration W	leek-day _				,							
		56-7	57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7
		1	1	1	1	1	1	1	1	1	1	1	i	1	1
MINDLOT	2	•				_									
AUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
REGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	1	0	0	0	0	0	0	0	0	0
BNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	1	0	0	0	0	0	0	0	0	0
RADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	1	0	0	0	0	0	0	0	0	0
BNORMAL RESPIRA.SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	Õ	0	Ô	0
	2000 ppm	0	0	. 0	0	0	0	0	0	0	ů	0	0	0	0
	4000 ppm	0	0	0	0	i	0	0	Ö	Ö	Ö	ŏ	0	0	0
JBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	Ŏ	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	Õ	Ö	0	0	0	0	0	0	0

(IIAN190)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : FEMALE

PAGE: 70

Clinical sign	Group Name	Admini	stration W	eek-day _											
		70-7	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
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
JAUNDISE	Control	0	0	0	٥	٥	0	٥	۰	•		_			
7nen/13L	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	mdd ooor	v	V	U	U	U	U	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
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ô
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
	4000 ppm	0	0	0	0	0	0	0	0	0	0	Ō	Ö	0	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	Ö	0	0	0	Ó	0
	2000 ppm	0	0	0	Õ	0	Ô	ő	Ö	Ö	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
BRADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	1000 ppm	0	0	0	0	0	0	ŏ	o O	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	Ö	0	0	0	0	0	0	0
	4900 ppm	0	0	0	0	0	Ō	0	0	Ö	0	0	0	0	0
ABNORMAL RESPIRA.SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	Ö	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	Ö	0	Ö	Ö	ő	0	0	0	0	0
	4000 ppm	0	0	0	0	Ö	Ö	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	. 1	0	0
	1000 ppm	0	Ö	Õ	0	Ö	Õ	ő	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	Ô	Ô	0	Ô	0	0	0	0	0	0	0	0	0

STUDY NO.: 0278
ANIMAL: RAT F344/DuCrj
REPORT TYPE: A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : FEMALE

PAGE: 71

Clinical sign	Group Name	Admini	istration W	leek-day			·								
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
AUNDISE	Control	0	0	0	0	0	0	0	٥	٥	٥	0	٥	٥	0
NONDISE	mag 0001	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	•	0	
	4000 ppili	V	U	U	U	U	U	U	U	U	U	U	0	0	0
REGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL RESPIRA.SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	2000 ppm	1	0	0	0	0	0	0	0	Ö	0	0	0	0	0
	4000 ppm	0	0	.0	0	1	0	Ŏ	0	0	Ô	0	0	0	0

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104 CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX: FEMALE

PAGE: 72

Clinical sign	Group Name	Λdmini	stration	Week-day				
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
		1	1	1	1	1	1	1
JAUNDISE	Control	0	0	0	0	0	0	0 ·
	1000 ppm	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0
	4000 ppm	0	1	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	1	0	0	0	0
	1000 ppm	1	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0
ABNORMAL RESPIRATION	Control	0	0	1	0	0	0	0
	1000 ppm	1	0	0	0	Ô	ő	Ő
	2000 ppm	0	0	0	Ö	Ö	ŏ	0
	4000 ppm	0	0	0	0	Ö	Ő	0
BRADYPNEA	Control	0	0	0	0	0	0	0
	1000 ppm	1	0	0	0	0	Ő	Ö
	2000 ppm	0	Ô	0	Ö	ő	0	0
	4000 ppm	0	Ö	0	Ö	Ö	0	0
ABNORMAL RESPIRA.SOUND	Control	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	ő	0
	2000 ppm	0	0	0	Ö	ŏ	0	0
	4000 ppm	0	0	0	Ō	Ö	ő	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0
	1000 ppm	1	0	0	ő	ő	0	0
	2000 ppm	0	0	Ö	Ŏ	0	0	0
	4000 ppm	0	0	0	0	1	0	1

APPENDIX B 1

BODY WEIGHT CHANGES: SUMMARY, RAT: MALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj UNIT : g

REPORT TYPE: A1 104 SEX: MALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

Group Name	Admin	stratio	n week											
	0		1		1		2		3		4		5	
Control	11 7 ±	4	120±	4	145±	7	175±	11	202±	13	226±	14	246±	15
1000 ppm	117±	4	120±	4	144土	7	173±	11	201±	15	224±	16	244±	18
2000 ppm	117±	4	120±	5	146±	7	175±	11	200±	14	222±	16	241±	17
4000 ppm	117±	4	120±	4	142±	6	168±	9**	192±	12**	214±	15**	232±	17**
Significant differer	nce; *:P≦(0.05	**: P ≤ 0.0	1			Test of Du	nnett						
(HAN260)														

ANIMAL : RAT F344/DuCrj

UNIT : g
REPORT TYPE : A1 104
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 2

roup Name	Admin	istration	week											
	6		7		8		9		10		11		12	
Control	263±	15	279±	15	293±	17	306±	17	316±	17	326±	18	334±	17
1000 pm	260±	18	276±	19	290±	19	303±	21	312±	21	321±	21	328±	21
2000 ppm	257±	19	272±	19	286±	20	298±	20	308±	20	317±	21	324±	20*
4000 ppm	248±	19**	262±	20**	275±	21**	287±	21**	297±	21**	306±	21**	312±	21**
												·····		
Significant difference;	*: P ≦	0.05 *	:*: P ≤ 0.0)1			Test of Du	ınnett						

(HAN260)

BAIS3

ANIMAL : RAT F344/DuCrj

UNIT : g

REPORT TYPE : A1 104

SEX : MALE

4000 ppm

322± 21**

328± 22**

BODY WEIGHT CHANGES ALL ANIMALS

351± 21**

(SUMMARY)

Group Name Administration week_ 22 13 26 30 34 Control 343± 18 350 ± 18 373± 20 389± 21 402± 22 417± 23 429± 23 1000 ppm 337 ± 22 344± 21 367± 22 386± 22 398± 22 412± 23 426± 24 2000 ppm 332± 20* 340± 20* 362± 22* 381 ± 22 394± 22 410± 23 423± 24

Significant difference : $*: P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (HAN260) BAIS 3

369± 23**

381士 24**

397± 23**

408± 25**

ANIMAL : RAT F344/DuCrj

UNIT : g REPORT TYPE : AI 104

SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)

ALL ANIMALS

38 438±	23	42 446±		46		50		54		58		62	
438±	23	446±											
		4401	24	452±	23	459±	23	461±	23	465±	23	467±	23
434±	25	443±	25	448±	25	455±	25	460±	26	463±	25	467±	26
431±	24	441±	25	447±	25	455±	24	452±	23	456±	23	461±	23
417±	25**	424±	26**	431±	26**	436±	26**	440±	27**	440±	26**	442±	25**
	431±	431± 24	431± 24 441±	431± 24 441± 25	431± 24 441± 25 447±	431± 24 441± 25 447± 25	431± 24 441± 25 447± 25 455±	431± 24 441± 25 447± 25 455± 24	431± 24 441± 25 447± 25 455± 24 452±	431± 24 441± 25 447± 25 455± 24 452± 23	431± 24 441± 25 447± 25 455± 24 452± 23 456±	431± 24 441± 25 447± 25 455± 24 452± 23 456± 23	431± 24 441± 25 447± 25 455± 24 452± 23 456± 23 461±

(HAN260)

BAIS3

ANIMAL : RAT F344/DuCrj UNIT : g

REPORT TYPE : A1 104 SEX : MALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

iroup Name	Admin	istration	week											
	66		70		74		78 .		82		86		90	
Control	471±	22	467±	24	466±	23	463± 29		463±	26	448±	48	455±	30
Mag 000	471±	27	470±	28	472±	27	466± 33		473±	30	475±	32*	468±	34
mqq 000S	462±	23	461±	23	459±	38	464± 25		460±	35	462±	28	462±	30
4000 ppm	444±	28**	440±	28**	440±	34**	444± 27	**	448±	37	445±	29	443±	31
Significant differen	nce; *: P ≦	0.05	**: P ≤ 0.0)1			Test of Dunne	tt						
(IIAN260)														

ANIMAL : RAT F344/DuCrj

UNIT : g
REPORT TYPE : A1 104

SEX : MALE

BODY WEIGHT CHANGES (SUMMARY) ALL ANIMALS

(HAN260)

BAIS 3

APPENDIX B 2

BODY WEIGHT CHANGES: SUMMARY, RAT: FEMALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj UNIT : g

REPORT TYPE : A1 104

SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)

ALL ANIMALS

Control 96±	nistration	1		1		2		3		4		5	
Control 96±													
	3	97±	4	110±	4	124±	5	135±	6	144±	7	154±	8
1000 ppm 96±	3	97±	3	109±	4	122±	5	133±	6	142±	7	152±	8
2000 ppm 96±	3	97±	3	110±	4	123±	5	134±	6	143±	7	151±	8
4000 ppm 96±	3	97±	3	107±	4**	118±	4**	128±	5**	135士	6**	144士	8**
4000 ppm 96±	3	97±	3	107±	4**	118±	4**	128±	5**	135±	6**	144±	

(IIAN260)

BAIS3

ANIMAL : RAT F344/DuCrj UNIT : g REPORT TYPE : A1 104

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

SEX : FEMALE

roup Name	Admin	stration	week									
	6		7	8	9		10		11		12	
Control	161±	8	168± 9	174± 10	179±	9	184±	10	189±	10	193±	11
1000 ppm	160±	9	166± 9	171± 9	177±	10	181±	10	187±	10	189土	10
2000 ppm	158±	9	164± 10	168± 10*	174±	11*	178±	11*	185±	12	187±	12
1000 ppm	150±	9**	155± 10**	160± 11*	* 166±	11**	170±	12**	177±	13**	179±	13**
Significant difference	e; *:P≦(0.05	** : P ≤ 0.01		Test of I	unnett						
HAN260)												

ANIMAL : RAT F344/DuCrj UNIT : g

REPORT TYPE : A1 104 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)

ALL ANIMALS

roup Name	Admin	istration	week											
	13		14		18		22		26		30		34	
Control	197±	10	199±	11	209±	12	215±	12	222±	13	233±	14	240±	14
1000 ppm	194±	11	196±	11	206±	12	214±	11	219±	12	231±	13	237±	13
2000 ppm	191±	12*	194±	12	204±	12	210±	13	217±	14	228±	15	234±	16
4000 ppm	184±	13**	186±	13**	196±	13**	205±	14**	210±	15**	222±	16**	227±	18**
Significant differe	nce; *: P ≦ (0.05 *	**: P ≤ 0.(01			Test of D	unnett						

(HAN260)

BAIS3

ANIMAL : RAT F344/DuCrj

UNIT : g
REPORT TYPE : A1 104

SEX : FEMALE

roup Name	Admin	istration	week											
	38		42		46		50		54		58		62	
Control	242±	15	248±	15	253±	16	263±	17	268±	17	271±	18	274±	19
1000 ppm	241±	13	248±	14	251±	15	261±	16	266±	18	273±	19	276±	20
2000 ppm	236±	15	243±	16	248±	17	259±	19	260±	19	264±	22	269±	24
4000 ppm	230±	16**	239±	18**	244±	19*	251±	21**	257±	24*	259士	25**	264±	26
Significant difference	; *:P≦	0.05 *	* : P ≤ 0.	01			Test of D	unnett						

(SUMMARY)

BODY WEIGHT CHANGES

ALL ANIMALS

(HAN260)

BAIS3

ANIMAL : RAT F344/DuCrj UNIT : g REPORT TYPE : A1 104

SEX : FEMALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

PAGE: 11

roup Name	Admin	istration	week											
	66		70		74		78		82		86		90	
Control	282±	20	288±	21	295±	22	301±	23	308±	24	314±	32	323±	26
1000 ppm	284±	21	291±	21	300±	23	305±	24	312±	24	321±	24	320±	28
2000 ррт	277±	24	284土	25	291±	26	298±	26	303±	31	316±	28	322±	28
4000 ppm	270±	26*	278±	27	281±	27*	286±	28*	293±	28*	298±	34*	306±	
Significant difference	pe; *:P≦	0.05	** : P ≤ 0.0)1			Test of Dur	nett						

BAIS 3

ANIMAL : RAT F344/DuCrj UNIT : g

REPORT TYPE : A1 104 SEX : FEMALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

PAGE: 12

Group Name	Λdmin	istratio	on week						 	
	94		98		102		104		 	
Control	326±	27	324±	28	324±	29	315±	31		
							0.00	01		
1000 ppm	323±	28	319±	32	320±	30	312±	32		
2000 ppm	329±	30	324±	31	322±	30	315±	26		
4000	207.1									
4000 ppm	307±	36*	309±	43*	301±	37**	293±	38*		
Significant difference;	*: P ≦	0.05	**: P ≤ 0.	01			Test of Du	ınnett		
(HAN260)								***************************************	 	

BAIS 3

APPENDIX C1

FOOD CONSUMPTION CHANGES: SUMMARY, RAT: MALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj UNIT : g

REPORT TYPE: A1 104

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

roup Name	Administration	week					
	1	2	3	4	5	6	7
Control	15.0± 0.8	16.5± 1.4	17.8± 1.6	18.7± 1.7	19.0± 1.6	18.9± 1.6	18.5± 1.4
1000 ppm	15.0± 0.9	16.3± 1.5	17.5± 1.6	18.3± 1.7	18.9± 1.9	18.6± 1.7	18.2± 1.6
2000 ppm	15.0± 0.9	16.2± 1.2	17.0± 1.5*	17.8± 1.5*	18.1± 1.7*	18.3± 1.7	17.8± 1.5
4000 ppm	14.3± 1.1**	15.0± 1.2**	16.1± 1.3**	17.0± 1.5**	17.6± 1.8**	17.5± 1.6**	17.2± 1.4**
Significant difference	$*: P \leq 0.05$	**: P ≤ 0.01		Test of Dunnett			
(HAN260)							

ANIMAL : RAT F344/DuCrj UNIT : g

REPORT TYPE : A1 104

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

Group Name	Administration	week	· · · · · · · · · · · · · · · · · · ·				
	8	9	10	11	12	13	14
Control	18.7± 1.4	19.2± 1.3	19.0± 1.4	19.1± 1.3	18.8± 1.1	18.9± 1.3	18.6± 1.3
1000 ppm	18.5± 1.5	19.0± 1.5	18.8± 1.4	18.6± 1.5	18.2± 1.3*	18.2± 1.4*	18.1± 1.4
2000 ppm	18.0± 1.6	18.4± 1.5*	18.3± 1.4	18.2± 1.2**	17.6± 1.2**	18.0± 1.3**	17.8± 1.3*
4000 ppm	17.4± 1.7**	17.8± 1.6**	17.9± 1.5**	18.2± 1.7*	17.4± 1.4**	17.9± 1.3**	17.5± 1.3**
Significant differer	nce; *: P ≤ 0.05 *	*: P ≤ 0.01		Test of Dunnett			
(HAN260)							

BAIS3

ANIMAL : RAT F341/DuCrj

UNIT : g

REPORT TYPE: A1 104

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

Group Name Administration week_ 22 26 30 34 38 42 Control 18.6± 1.6 18.7± 1.6 18.7± 1.2 18.8± 1.4 18.7 ± 1.3 18.9± 1.3 18.8± 1.2 1000 ppm 18.2± 1.3 18.4± 1.1 18.3± 1.2* 18.3 ± 1.2 18.5 ± 1.2 18.3± 1.2* 18.4± 1.1 2000 ppm 17.8± 1.4* 18.4± 1.4 18.3± 1.1 18.2± 1.1 18.4± 1.1 18.2± 1.2* 18.4± 1.1 4000 ppm 17.6± 1.4** 17.9± 1.3** 18.4± 1.0 18.1± 1.6* 18.5 ± 1.2 18.3± 1.2* 18.0± 1.2**

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

(HAN260)

BAIS3

ANIMAL : RAT F344/DuCrj UNIT : g

REPORT TYPE : A1 104

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

coup Name	Administrati	on week					
	46	50	54	58	62	66	70
Control	18.5± 1.1	18.6± 1.1	18.1± 1.1	18.9± 1.0	18.6± 1.3	18.7± 1.7	18.5± 1.7
mag 000	18.1± 0.9	18.1± 1.0	18.5± 1.0	19.0± 1.0	18.8± 1.2	18.8± 1.1	18.5± 1.1
MQQ 000	18.3± 1.0	18.5± 1.0	17.3± 0.9**	18.6± 0.9	18.5± 1.1	18.5± 1.0	18.2± 1.0
Maga 0001	18.2± 1.1	18.1± 1.4	18.2± 1.1	18.4± 1.0*	18.7± 1.2	18.1± 1.7	18.1± 1.5
Significant difference;	*: P ≤ 0.05	** : P ≤ 0.01		Test of Dunnett			
AN260)							

ANIMAL : RAT F344/DuCrj UNIT : g

ALL ANIMALS

REPORT TYPE : A1 104 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)

roup Name	Administrati	an week					
	74	78	82	86	90	94	98
Control	19.0± 1.6	19.0± 2.5	19.3± 2.5	17.8± 3.2	18.5± 2.3	18.3± 2.0	17.9± 2.3
MQQ 000	18.9± 1.1	18.4± 2.8	18.7± 1.6	19.5± 1.6*	18.8± 2.3	18.3± 1.8	18.0± 1.3
maq 000	18.6± 2.7	19.0± 1.3	18.2± 2.9	18.6± 1.3	19.4± 2.0	18.0± 2.1	17.9± 2.5
Mada 000	19.0± 2.6	18.9± 1.4	18.8± 1.7	20.1± 2.2**	20.0± 2.0**	18.6± 3.7	19.5± 4.6**
Significant difference;	* : P ≤ 0.05	** : P ≤ 0.01		Test of Dunnett			
AN260)							1

BAIS3

ANIMAL : RAT F344/DuCrj UNIT : g REPORT TYPE : AI 104 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

SEX : MALE				PAGE: 6
Group Name	Administrat 102	ion week		
Control	17.2± 4.3	17.3± 2.9		
1000 ppm	18.3± 2.1	17.4± 1.3		
2000 ppm	17.5± 2.5	16.6± 3.4		
4000 ppm	19.0± 2.8*	18.6± 4.6**		
Significant difference;	*: P ≤ 0.05	** : P ≤ 0.01	Test of Dunnett	
(HAN260)				BAIS3

APPENDIX C 2

FOOD CONSUMPTION CHANGES: SUMMARY, RAT: FEMALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

UNIT : g
REPORT TYPE : A1 104
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

Group Name	Administration week								
	1	2	3	4	5	6	7		
Control	12.0± 0.7	12.2± 0.8	12.0± 0.9	12.4± 0.9	13.1± 1.3	12.9± 1.0	12.6± 1.1		
1000 ppm	12.0± 0.8	12.1± 1.0	12.1± 1.0	12.5± 1.0	13.0± 1.0	12.6± 1.1	12.5± 1.1		
2000 ppm	12.0± 0.8	11.9± 0.9	12.0± 1.0	12.3± 1.1	12.6± 1.4	12.4± 1.6*	11.8± 1.5**		
4000 ppm	11.2± 0.9**	11.0± 0.8**	11.4± 0.8**	11.4士 0.9**	12.1± 1.1**	11.8± 1.3**	11.3± 1.5**		
Significant differen	nce; $*: P \leq 0.05$	**: P ≤ 0.01		Test of Dunnett					
(HAN260)						, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,	· · · · · · · · · · · · · · · · · · ·		

ANIMAL : RAT F344/DuCrj

UNIT : g

REPORT TYPE : A1 104

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 8

roup Name	Administration	week					
	8	9	10	11	12	. 13	14
Cantral	12.6± 1.3	13.1± 1.3	12.9± 1.2	12.8± 1.4	13.2± 1.5	13.2± 1.6	12.8± 1.2
1000 ppm	12.4± 1.0	12.7± 1.1	12.8± 1.4	13.0± 1.2	12.7± 1.4	12.8± 1.4	12.9± 1.5
2000 ppm	11.8± 1.3**	12.3± 1.8**	12.5± 1.7	12.8± 1.7	12.3± 1.5**	12.5± 1.4	12.3± 1.2
4000 ppm	11.4± 1.6**	11.9± 1.3**	11.9± 1.5**	12.3± 1.4	11.9± 1.5**	12.5± 1.4	12.1± 1.2*
						-x	
Significant differe	nce; *: P ≤ 0.05	* : P ≦ 0.01		Test of Dunnett			

(HAN260)

BAIS3

ANIMAL : RAT F344/DuCrj

UNIT : g
REPORT TYPE : A1 104

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 9

Group Name	Administration week								
	18	22	26	30	34	38	42		
Control	12.4± 1.5	12.9± 1.7	12.5± 1.1	13.5± 2.0	12.9± 1.2	12.6± 1.0	13.3± 1.1		
1000 ppm	12.7± 1.3	12.8± 1.1	12.9± 1.2	13.7± 1.6	13.3± 1.5	12.8± 0.9	13.2± 1.2		
ntqq 000	12.3± 1.2	12.3± 1.3*	12.4± 1.3	13.2± 1.5	12.7± 1.3	12.2± 1.0	12.8± 0.9		
4000 ppm	12.1± 1.3	12.7± 1.2	12.6± 1.4	13.3± 1.4	13.1± 1.3	13.0± 1.0	13.2± 1.1		
Significant differer	nce; *: P ≦ 0.05	** : P ≤ 0.01		Test of Dunnett					

(HAN260)

BAIS3

ANIMAL : RAT F344/DuCrj

UNIT : g
REPORT TYPE : A1 104
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

Group Name	Administration	week					
	46	50	54	58	62	66	70
Control	13.2± 1.0	13.7± 1.3	12.9± 0.9	13.2± 1.0	13.2± 1.1	13.7± 1.0	13.7± 1.8
1000 ppm	13.0± 1.1	13.5± 1.2	13.1± 1.2	13.9± 1.1**	13.1± 1.2	13.9± 1.1	14.0± 1.3
2000 ppm	12.8± 0.9	13.3± 1.4	12.2± 1.3**	12.7± 1.0	13.0± 1.1	13.6± 1.0	13.7± 1.0
mqq 000h	13.1± 1.2	13.5± 1.3	13.3± 1.3	12.9± 1.0	13.6± 1.4	14.0± 1.2	14.3± 1.2
Significant difference	ce; *: P ≦ 0.05	** : P ≤ 0.01		Test of Dunnett			
(HAN260)							

ANIMAL : RAT F344/DuCrj UNIT : g

REPORT TYPE : A1 104 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 11

roup Name	Administration week							
	74	78	82	86	90	94	98	
Control	14.2± 1.2	14.3± 1.3	14.3± 1.3	14.8± 1.5	15.1± 1.5	14.5± 1.3	14.4± 2.5	
mqq 000	14.9± 1.2*	14.7± 1.4	14.6± 1.2	15.1± 1.7	14.3± 2.6	14.6± 2.0	13.6± 2.7	
mqq 000	14.3± 1.4	14.8± 1.3	13.8± 2.0	15.1± 1.7	15.4± 1.7	15.0± 1.9	13.7± 2.8	
1000 ppm	14.4± 2.0	14.8± 1.1	14.7± 1.6	15.6± 2.8**	15.6± 1.4	14.6± 2.6	15.2± 2.5	
Significant difference;	*: $P \le 0.05$	**: $P \leq 0.01$		Test of Dunnett				
(AN260)					······································			

(HAN260)

BAIS3

ANIMAL : RAT F344/DuCrj UNIT : g

REPORT TYPE : A1 104

SEX: FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE: 12

Group Name	Administrati	an week		
	102	104		
Control	15.2± 1.7	13.6± 2.0		
1000 ppm	14.0± 2.7	13.3± 2.2		
2000 ppm	14.5± 2.4	13.7± 1.7		
4000 ppm	14.5± 3.4	13.9± 3.0		
	14.02 0.4	10.01 0.0		
Significant difference;	*: P ≤ 0.05	** : P ≤ 0.01	Test of Dunnett	
(HAN260)			TOSE OF PURIOEE	

(HAN260)

BAIS 3

APPENDIX D1

HEMATOLOGY: SUMMARY, RAT: MALE

ANIMAL : RAT F344/DuCrj
MEASURE. TIME : 1
SEX : MALE REPOR

HEMATOLOGY (SUMMARY) ALL ANIMALS (105W)

Group Name	NO. of Animals	RED BLOOD CEL 1 O ⁶ /µℓ	L HEMOGLOB g∕dl	BIN	HEMATOC %	RIT	MCV f Q		MCH pg		MCHC g∕dl		PLATELE 1 0³/µ	
Control	32	7.80± 1.70	13.3±	3.4	40.0±	8.4	51.4±	2.4	16.9±	1.6	32.9±	2.6	1129±	376
1000 ppm	43	8.17± 1.85	14.3±	3.2	42.8±	8.8	52.8±	4.0	17.7±	2.1	33.3±	2.0	982±	288
2000 ppm	36	7.93± 1.63	14.2±	2.7	42.4±	7.1	54.1±	5.3**	17.9±	1.1**	33.3±	2.0	901±	189*
4000 ppm	27	7.65± 2.09	13.5±	3.2	40.8±	8.5	54.7±	6,5**	18.0±	1.9**	32.9±	2.1	980±	225

BAIS3 (HCL070)

STUDY NO. : 0278 ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1

HEMATOLOGY (SUMMARY) ALL ANIMALS (105W)

Group Name	NO. of	WBC	,	Dit	ferentia	L WBC (9	6)										
	Animals	1 0³/	μl	N-BAND		N-SEG	·	EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	32	6.09±	1.56	1±	1	60±	9	1±	1	0±	0	4±	2	30±	9	4±	3
1000 ppm	43	8.63±	17.50	1 ±	1	54±	13	1±	1	0±	0	5±	2	33±	11	6±	13
2000 ppm	36	11.04±	29.70	1±	1	53±	12	1±	1	0±	0	5±	2	34±	10	6±	14
4000 ppm	27	8.93±	9,95	1±	1	54±	13	1±	1	0±	0	5±	2	31士	10	8±	15
Significar	nt difference	; *:P:	≦ 0.05	**: P ≦	0.01			Test	of Dunr	nett	-						

APPENDIX D 2

HEMATOLOGY: SUMMARY, RAT: FEMALE

STUDY NO. : 0278 ANIMAL : RAT F344/DuCrj

HEMATOLOGY (SUMMARY) ALL ANIMALS (105W)

MEASURE. TIME: 1

SEX : FEMALE

REPORT TYPE : A1

PAGE: 3

Group Name	NO. of Animals	RED BLO	DOD CELL	g ∕dl HEMOGLO	BIN	HEMATOC %	RIT	MCV f Q		MCH Pg		g∕dî MCHC		PLATELE 1 O³∕µ	
Control	44	8.00±	0.85	14.7±	1.4	43.0±	3,2	54.1±	3.3	18.4±	1.0	34.1±	1.5	728±	149
1000 ppm	38	8.31±	0.90	15.1±	2.0	44.0±	5.1	52.9±	1.8	18.1±	1.1	34.1±	1.6	709±	242
2000 ppm	42	8.29±	1.12*	15.2±	1.8	44.3±	4.6*	53.9±	3.6	18.4±	1.1	34.2±	1.8	719±	174
4000 ppm	29	8.28±	1.52**	15.2±	2.1	45.0±	5.6**	55.9±	9.3	18.8±	2,4	33.7±	1.4	708±	135

(HCL070)

ANIMAL : RAT F344/DuCrj MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY) ALL ANIMALS (105W)

SEX : FEMALE	nerun	T TYPE : A1													PAGE	E: 4
Group Name	NO. of Animals	WBC 1 O³∕µl	Dit N-BAND	fferentia	N-SEG	%)	EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	44	3.37± 2.03	1±	1	51±	13	1±	1	0±	0	5±	2	37±	11	5±	11
1000 ppm	38	3.80± 2.85	1±	2	50±	11	1±	1	0±	0	5±	2	35±	9	8:上	13
2000 ppm	42	24.87± 141.29	2±	2	49±	13	1±	1	0±	0	5±	2	35±	10	8±	15
4000 ppm	29	6.92± 19.05	2±	4	47±	14	1±	1	0±	0	4±	2	36±	13	10±	18
Significant	difference	; *: P ≤ 0.05	**: P ≦	0.01			Test	of Dunr	nett				0	·····		
(IICL070)																BAIS 3

APPENDIX E 1

BIOCHEMISTRY: SUMMARY, RAT: MALE

ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1

SEX: MALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

PAGE: 1 Group Name NO. of TOTAL PROTEIN ALBUMIN A/G RATIO T-BILIRUBIN GLUCOSE T-CHOLESTEROL TRIGLYCERIDE g/dl Animals g/dl mg∕dl mg/dl mg/dl mg/dl Control 32 6.4± 0.4 $3.1\pm$ 0.9± 0.2 0.1 0.18± 0.04 144士 29 $222\pm$ 61 216± 119 1000 ppm 43 $6.3 \pm$ 0.2 $3.2\pm$ 0.2 1.0± 0.1 0.19± 0.04 $137 \pm$ 25 $169 \pm$ 42** 142士 86** 2000 ppm 37 $6.2 \pm$ 0.4 $3.2\pm$ 0.2 1.1± 0.1** 0.20 ± 0.08 $139 \pm$ 18 169± 57** 138± 109** 27 4000 ppm 6.0 ± 0.6 2.9± 0.4 1.0± 0.1 0.21 ± 0.08 132± 26 171± 59** 103± 92** Significant defference; $*: P \leq 0.05$ ** : $P \le 0.01$ Test of Dunnett

(IICL074)

STUDY NO.: 0278 ANIMAL: RAT F344/DuCrj

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

MEASURE. TIME: 1

SEX : MALE

REPORT TYPE : A1

PAGE: 2

Group Name	NO. of Animals	PHOSPHO mg/dl	LIPID	GOT IU/l		GPT I U∕ℓ		LDH IU/	2	ALP IU/J	ı	G-GTP IU∕£		CPK IU/s	1
Control	32	320±	83	64±	23	37±	17	201±	40	158±	46	8±	4	98±	20
1000 ppm	43	249±	60**	100±	50**	47±	26*	334±	464**	157±	69	6±	3	103±	54
mqq 000S	37	252±	85**	98±	56**	45±	19*	250±	156	161±	86	7±	6	154±	383
4000 ppm	27	259±	89**	106±	62**	44±	18	222±	56	190±	119	9±	6	114±	105

(IICL074)

ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1

SEX : MALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

PAGE: 3 Group Name NO. of UREA NITROGEN CREATININE SODIUM POTASSIUM CHLORIDE CALCIUM INORGANIC PHOSPHORUS Animals mg/dl mg/dl mEq∕ ℓ mEq/l mEq∕ l mg/dl mg/dl Control 32 26.2± 6.3 0.8± 0.2 141± 3.7± 0.3 104± 2 10.6± 0.6 4.3± 0.7 1000 ppm 43 26.4± 20.8 $0.7 \pm$ 0.2 141± 1 $3.8 \pm$ 0.5 105± 2 10.6± 0.4 4.2± 1.1 2000 ppm 37 23.6± 6.7 0.7± 0.2 141± 1 $3.9 \pm$ 0.5* $105 \pm$ 2* 10.6± 0.9 4.3± 1.3 4000 ppm 27 26.5 ± 19.5 $0.7\pm$ 0.3 142± $4.0 \pm$ 0.3** 106± 2** 10.5± 0.8 4.6± 1.4 Significant defference : $*: P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(HCL074)

APPENDIX E 2

BIOCHEMISTRY: SUMMARY, RAT: FEMALE

ANIMAL : RAT F344/DuCrj MEASURE. TIME : 1

MEASURE. TIME : SEX : FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

Group Name	NO. of Animals	g∕dl g∕dl		aLBUMIN g∕dl		A/G RAT	10	T-BILI mg/dl		GLUCOSE mg∕dl		T-CHOLES	STEROL	TRIGLYC mg∕dl	ERIDE
Control	44	6.7±	0.4	3.7±	0.2	1.2±	0.1	0.19±	0.12	142±	16	179±	56	164±	198
1000 ppm	38	6.7±	0.4	3.8±	0.3	1.3±	0.1	0.17±	0.04	133±	16*	173±	38	66±	26**
mqq 000	42	6.8±	0.4	3.8±	0.3	1.3±	0.1	0.18±	0.03	130±	18**	209±	65*	68±	34**
mag 0001	29	6.6±	0.4	3.7±	0.2	1.3±	0.1	0.20±	0.12	131±	12*	201±	59	66±	39**

(HCL074)

BAIS 3

ANIMAL : RAT F344/DuCrj MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

		mg/dl		TOD I U / I	ļ	GPT IU∕↓		I U/	Q	ALP IU/	ļ,	G-GTP IU/Q		CPK IU/s	2
Control	44	306±	90	104±	79	54±	25	246±	74	118±	48	5±	2	91±	16
Mqq 0001	38	281 ±	57	167±	60**	86±	32**	325±	123**	133±	53	5±	3	214±	634**
maa 000S	42	324±	97	170±	111**	88±	43**	393±	304**	145±	76	5±	6	115±	28**
4000 ppm	29	311±	83	113±	57	63±	23	303±	188	137±	66	6±	4	103±	15**

PAGE: 5

ANIMAL : RAT F344/DuCrj MEASURE. TIME : 1

SEX : FEMALE

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

SEX : FEMALE	REPORT	TYPE: A1													PAGE: 6
Group Name	NO. of Animals	UREA N	ITROGEN	CREATIN mg∕dl	INE	SODIUM mEq/Q		POTASSI mEq/		CHLORIDE mEq/Q		CALCIUM mg/dl		INORGAN mg∕dl	NIC PHOSPHORUS
Control	44	16.2±	2.5	0.5±	0.1	140±	2	3.6±	0.4	103±	2	10.5±	0.4	3.5±	0.7
1000 ppm	38	16.5±	3.0	0.5±	0.1	140±	2	3.8±	0.4	103±	2	10.4±	0.3	3.8±	1.0
2000 ppm	42	21.3±	32.3	0.6±	0.8	140±	2	3.8±	0.8	103±	3	10.5±	0.4	4.4±	3.8
4000 ppm	29	15.9±	1.8	0.5±	0.1	139±	2	3.9±	0.5**	104±	2	10.5±	0.4	4.0±	0.7*
Significant	defference;	*: P ≦	0.05	**: P ≤ 0.0	1		 	Test of Dur	nett		•				
(IICL074)													<u> </u>		BAISS

APPENDIX F1

URINALYSIS: SUMMARY, RAT: MALE

URINALYSIS

ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1

SEX : MALE

REPORT TYPE : A1

PAGE: 1

roup Name	NO. of	pH_							Protein	Glucose	Ketane bady	Bilirubin
	Animals	5.0	6.0	6.5	7.0	7.5	8.0	8.5 CHI	- ± + 2+ 3+ 4+ CHI	- ± + 2+ 3+ 4+ CHI	- ± + 2+ 3+ 4+ CHI	- + 2+ 3+ CHI
Control	32	0	1	5	8	12	6	0	0 0 0 0 4 28	32 0 0 0 0 0	32 0 0 0 0 0	32 0 0 0
1000 ppm	43	0	0	3	13	17	10	0	0 0 0 0 13 30	43 0 0 0 0 0	43 0 0 0 0 0	43 0 0 0
mqq 0002	39	0	1	8	15	10	5	0	0 0 1 3 8 27	39 0 0 0 0 0	39 0 0 0 0 0	38 1 0 0
4000 ppm	29	0	3	12	5	7	2	0	0 1 0 1 6 21	29 0 0 0 0 0	29 0 0 0 0 0	27 1 0 1

URINALYSIS

ANIMAL : RAT F344/DuCrj

MEASURE, TIME: 1

SEX : MALE

REPORT TYPE : A1

Group Name	NO. of Animals	0ccult blood - ± + 2+ 3+ CHI	Urabilinagen ± + 2+ 3+ 4+ CHI			
Control	32	31 1 0 0 0	32 0 0 0 0			
1000 ppm	43	43 0 0 0 0	43 0 0 0 0			
2000 ppm	39	39 0 0 0 0	38 1 0 0 0			
4000 ppm	29	28 1 0 0 0	29 0 0 0 0			
Significan	nt difference	; *:P≦0.05 **	: P ≤ 0.01	Test of CHI SQUARE		
(HCL101)					 	BAIS3

APPENDIX F 2

URINALYSIS: SUMMARY, RAT: FEMALE

URINALYSIS

ANIMAL : RAT F344/DuCrj

MEASURE, TIME: 1

SEX : FEMALE

REPORT TYPE : A1

roup Name	NO. of	_Hq							Protein	Glucase	Ketone body	Bilirubin
	Animals	5.0	6.0	6.5	7.0	7.5	8.0	8.5 CHI	- ± + 2+ 3+ 4+ CHI	- ± + 2+ 3+ 4+ CHI	- ± + 2+ 3+ 4+ CHI	- + 2+ 3+ CHI
Control	45	0	2	1	19	14	9	0	0 0 1 2 11 31	45 0 0 0 0 0	44 1 0 0 0 0	45 0 0 0
1000 ppm	40	0	3	6	13	11	6	1	0 0 3 7 10 20	40 0 0 0 0 0	40 0 0 0 0 0	40 0 0 0
2000 ppm	43	0	1	3	18	12	9	0	0 0 0 7 12 24	43 0 0 0 0 0	43 0 0 0 0 0	43 0 0 0
4000 ppm	31	0	1	4	9	10	7	0	0 1 2 5 11 12	31 0 0 0 0 0	31 0 0 0 0 0	30 0 1 0

BAIS3

URINALYSIS

ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1

SEX : FEMALE

REPORT TYPE : A1

					PAGE: 4
Group Name	NO. of Animals	0ccult blood - ± + 2+ 3+ CHI	Urobilinogen ± + 2+ 3+ 4+ CHI		
Control	45	44 0 0 0 1	45 0 0 0 0		
1000 ppm	40	40 0 0 0 0	40 0 0 0 0		
2000 ppm	43	43 0 0 0 0	43 0 0 0 0		
4000 ppm	31	30 1 0 0 0	30 1 0 0 0		
Significant	difference	; *: P ≤ 0.05 **	: P ≤ 0.01	Test of CHI SQUARE	
(IICL101)					BAIS 3

APPENDIX G1

GROSS FINDINGS: SUMMARY, RAT: MALE: ALL ANIMALS

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : MALE FINDINGS (SUMMARY)
ALL ANIMALS (0-105W)

)rgan	Findings		ntrol (%)	1000 ppm 50 (%)	2000 ppm 50 (%)	4000 ppm 50 (%)
skin/app	nodule	3	(6)	3 (6)	2 (4)	5 (10)
subcutis	jaundice	0	(0)	1 (2)	0 (0)	0 (0)
	nodule	1	(2)	1 (2)	0 (0)	0 (0)
	mass	. 5	(10)	12 (24)	17 (34)	20 (40)
lung	red	0	(0)	0 (0)	0 (0)	1 (2)
	white zone	2	(4)	0 (0)	0 (0)	1 (2)
	red zone	0	(0)	0 (0)	1 (2)	0 (0)
	red patch	1	(2)	0 (0)	0 (0)	0 (0)
	nodule	7	(14)	2 (4)	2 (4)	3 (6)
ymph nade	enlarged	2	(4)	2 (4)	2 (4)	2 (4)
hymus	nodute	0	(0)	0 (0)	1 (2)	0 (0)
pleen	enlarged	3	(6)	4 (8)	9 (18)	6 (12)
	white zone	0	(0)	0 (0)	1 (2)	0 (0)
	nodule	0	(0)	1 (2)	1 (2)	2 (4)
	deformed	1	(2)	0 (0)	1 (2)	5 (10)
eart	white zone	0	(0)	1 (2)	2 (4)	1 (2)
rtery/aort	hard	1	(2)	0 (0)	0 (0)	0 (0)
ongue	nodule	0	(0)	1 (2)	0 (0)	0 (0)
orestomach	nodule	3	(6)	0 (0)	0 (0)	1 (2)
٠	ulcer	3	(6)	0 (0)	0 (0)	1 (2)
l stomach	ulcer	2	(4)	0 (0)	1 (2)	0 (0)
mall intes	thick	2	(4)	0 (0)	0 (0)	0 (0)

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

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : MALE

gan	Findings	Group Name NO. of Animals	Control 50 (%)	1000 ppm 50 (%)	2000 ppm 50 (%)	4000 ppm 50 (%)
arge intes	nodule		0 (0)	0 (0)	0 (0)	1 (2)
	fluid:black		1 (2)	0 (0)	0 (0)	0 (0)
iver	enlarged		0 (0)	1 (2)	0 (0)	0 (0)
	pale		2 (4)	0 (0)	0 (0)	2 (4)
	white zone		0 (0)	0 (0)	1 (2)	1 (2)
	brown zone		1 (2)	0 (0)	0 (0)	0 (0)
	nodule		2 (4)	0 (0)	2 (4)	2 (4)
	rough		0 (0)	0 (0)	1 (2)	2 (4)
	herniation		1 (2)	1 (2)	2 (4)	4 (8)
ancreas	nodule		1 (2)	2 (4)	0 (0)	2 (4)
idney	enlarged		0 (0)	0 (0)	0 (0)	1 (2)
	pale		1 (2)	0 (0)	0 (0)	0 (0)
	white zone		0 (0)	0 (0)	2 (4)	0 (0)
	nodule		1 (2)	2 (4)	0 (0)	0 (0)
	cyst		1 (2)	0 (0)	1 (2)	0 (0)
	deformed		0 (0)	1 (2)	0 (0)	0 (0)
	granular		41 (82)	38 (76)	32 (64)	31 (62)
	nodular		1 (2)	0 (0)	0 (0)	0 (0)
rin bladd	urine:marked retention		0 (0)	1 (2)	1 (2)	0 (0)
	urine:red		1 (2)	0 (0)	0 (0)	2 (4)
ituitary	enlarged		7 (14)	0 (0)	4 (8)	4 (8)
	red zone		3 (6)	1 (2)	1 (2)	2 (4)

ANIMAL : RAT F344/DuCrj

: MALE

REPORT TYPE : A1
SEX : MALI

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

rgan	Findings	Group Name NO. of Animals	Control 50 (%)	1000 ppm 50 (%)	2000 ppm 50 (%)	4000 ppm 50 (%)
ituitary	nodule		6 (12)	5 (10)	5 (10)	5 (10)
	cyst		0 (0)	1 (2)	0 (0)	0 (0)
hyroid	enlarged		2 (4)	2 (4)	2 (4)	2 (4)
	nodule		4 (8)	0 (0)	1 (2)	4 (8)
drenal	enlarged		0 (0)	0 (0)	1 (2)	1 (2)
estis	enlarged		0 (0)	0 (0)	0 (0)	1 (2)
	atrophic		1 (2)	0 (0)	1 (2)	2 (4)
	nadule		40 (80)	47 (94)	46 (92)	41 (82)
rain	red zone		0 (0)	0 (0)	1 (2)	0 (0)
pinal cord	hemorrhage		1 (2)	0 (0)	0 (0)	0 (0)
уе	white		2 (4)	1 (2)	4 (8)	0 (0)
	exophthalmos		0 (0)	0 (0)	1 (2)	0 (0)
ymbal gl	nodule		0 (0)	1 (2)	0 (0)	0 (0)
leura	nodule		1 (2)	1 (2)	1 (2)	0 (0)
ediastinum	mass		1 (2)	0 (0)	0 (0)	0 (0)
eritoneum	nodule		2 (4)	1 (2)	0 (0)	7 (14)
	mass		1 (2)	0 (0)	0 (0)	0 (0)
etroperit	hemorrhage		1 (2)	0 (0)	0 (0)	0 (0)
	mass		0 (0)	0 (0)	0 (0)	1 (2)
	cyst		0 (0)	0 (0)	1 (2)	0 (0)
bdominal c	red		0 (0)	0 (0)	0 (0)	1 (2)
	hemorrhage		1 (2)	0 (0)	0 (0)	1 (2)

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : MALE PAGE: 4

Organ	Findings	Group Name Control NO. of Animals 50 (%)	1000 ppm 50 (%)	2000 ppm 50 (%)	4000 ppm 50 (%)
abdominal c	ascites	3 (6)	1 (2)	1 (2)	6 (12)
mesenterium	nodule	0 (0)	0 (0)	0 (0)	1 (2)
	nodular	0 (0)	1 (2)	0 (0)	0 (0)
thoracic ca	ploural fluid	1 (2)	2 (4)	2 (4)	5 (10)
rther	swollen	0 (0)	0 (0)	0 (0)	1 (2)
	nodule	1 (2)	0 (0)	0 (0)	0 (0)
	tail:nodule	0 (0)	1 (2)	1 (2)	0 (0)
	ear:nodule	1 (2)	0 (0)	3 (6)	0 (0)
whole body	anemic	1 (2)	1 (2)	0 (0)	0 (0)

(IIPT080)

APPENDIX G 2

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

STUDY NO. : 0278
ANIMAL : RAT F344/DuC-j
REPORT TYPE : A1

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

SEX : MALE

Organ	Findings	Group Name NO. of Animals	Control 18 (%)	1000 ppm 7 (%)	2000 ppm 12 (%)	4000 ppm 22 (%)
skin/app	nodule		1 (6)	0 (0)	1 (8)	1 (5)
subcutis	jaundice		0 (0)	1 (14)	_ 0 (0)	0 (0)
	mass		3 (17)	0 (0)	5 (42)	5 (23)
lung	red		0 (0)	0 (0)	0 (0)	1 (5)
	red patch		1 (6)	0 (0)	0 (0)	0 (0)
	nodule		2 (11)	0 (0)	1 (8)	2 (9)
lymph node	enlarged		2 (11)	1 (14)	1 (8)	1 (5)
thymus	nodule		0 (0)	0 (0)	1 (8)	0 (0)
spleen	enlarged		1 (6)	2 (29)	5 (42)	4 (18)
	nodule		0 (0)	0 (0)	0 (0)	1 (5)
	deformed		0 (0)	0 (0)	0 (0)	1 (5)
heart	white zone		0 (0)	1 (14)	0 (0)	1 (5)
artery/aort	hard		1 (6)	0 (0)	0 (0)	0 (0)
forestomach	nodule		2 (11)	0 (0)	0 (0)	1 (5)
	ulcer		3 (17)	0 (0)	0 (0)	1 (5)
gl stomach	ulcer		2 (11)	0 (0)	1 (8)	0 (0)
small intes	thick		2 (11)	0 (0)	0 (0)	0 (0)
large intes	fluid:black		1 (6)	0 (0)	0 (0)	0 (0)
liver	enlarged		0 (0)	1 (14)	0 (0)	0 (0)
	pale		2 (11)	0 (0)	0 (0)	2 (9)
	nodule		1 (6)	0 (0)	0 (0)	0 (0)
	rough		0 (0)	0 (0)	1 (8)	1 (5)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

GROSS FINDINGS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

SEX : MALE

rgan	Findings	Group Name NO. of Animals	Control 18 (%)	1000 ppm 7 (%)	2000 ppm 12 (%)	4000 ppm 22' (%)
iver	herniation		1 (6)	0 (0)	1 (8)	1 (5)
ancreas	nodule		0 (0)	1 (14)	0 (0)	1 (5)
idney	enlarged		0 (0)	0 (0)	0 (0)	1 (5)
	pale		1 (6)	0 (0)	0 (0)	0 (0)
	white zone		0 (0)	0 (0)	1 (8)	0 (0)
	nodule		1 (6)	2 (29)	0 (0)	0 (0)
	cyst		1 (6)	0 (0)	0 (0)	0 (0)
	deformed		0 (0)	1 (14)	0 (0)	0 (0)
	granular		10 (56)	0 (0)	5 (42)	5 (23)
in bladd	urine:marked retention		0 (0)	0 (0)	1 (8)	0 (0)
	urine:red		1 (6)	0 (0)	0 (0)	2 (9)
ituitary	enlarged		6 (33)	0 (0)	2 (17)	1 (5)
	red zone		2 (11)	0 (0)	1 (8)	2 (9)
	nodule		0 (0)	0 (0)	1 (8)	1 (5)
	cyst		0 (0)	1 (14)	0 (0)	0 (0)
nyroid	enlarged		0 (0)	1 (14)	0 (0)	1 (5)
	nodule		1 (6)	0 (0)	0 (0)	1 (5)
drenal	enlarged		0 (0)	0 (0)	0 (0)	1 (5)
estis	enlarged		0 (0)	0 (0)	0 (0)	1 (5)
	atrophic		1 (6)	0 (0)	1 (8)	1 (5)
	nodule		10 (56)	4 (57)	8 (67)	15 (68)
ain	red zone		0 (0)	0 (0)	1 (8)	0 (0)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE

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

PAGE: 3

Organ	Findings	Group Name NO. of Animals	Control 18 (%)	1000 ppm 7 (%)	2000 ppm 12 (%)	4000 ppm 22 (%)
spinal cord	hemorrhage		1 (6)	0 (0)	0 (0)	0 (0)
эуе	white		0 (0)	0 (0)	1 (8)	0 (0)
ymbal gl	nodule		0 (0)	1 (14)	0 (0)	0 (0)
leura	nodule		1 (6)	1 (14)	1 (8)	0 (0)
ediastinum	mass		1 (6)	0 (0)	0 (0)	0 (0)
eritoneum	nodule		1 (6)	1 (14)	0 (0)	3 (14)
	mass		1 (6)	0 (0)	0 (0)	0 (0)
etroperit	hemorrhage		1 (6)	0 (0)	0 (0)	0 (0)
	mass		0 (0)	0 (0)	0 (0)	1 (5)
odominal c	hemorrhage		1 (6)	0 (0)	0 (0)	1 (5)
	ascites		2 (11)	1 (14)	1 (8)	3 (14)
esenterium	nodule		0 (0)	0 (0)	0 (0)	1 (5)
	nodular		0 (0)	1 (14)	0 (0)	0 (0)
noracic ca	pleural fluid		1 (6)	1 (14)	0 (0)	5 (23)
ther	swollen		0 (0)	0 (0)	0 (0)	1 (5)
	nodule		1 (6)	0 (0)	0 (0)	0 (0)
	tail:nodule		0 (0)	0 (0)	1 (8)	0 (0)
	ear:nodule		0 (0)	0 (0)	1 (8)	0 (0)
hale body	anemic		1 (6)	1 (14)	0 (0)	0 (0)

(HPT080)

APPENDIX G3

GROSS FINDINGS: SUMMARY, RAT : MALE : SACRIFICED ANIMALS

ANIMAL : RAT F344/DuCrj

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (105W)

REPORT TYPE : A1 SEX : MALE

Group Name Control 1000 ppm 2000 ppm 4000 ppm 0rgan Findings_ NO. of Animals 32 (%) 43 (%) 38 (%) 28 (%) skin/app nodule 2 (6) 3 (7) 1 (3) 4 (14) subcutis nodule 1 (3) 1 (2) 0 (0) 0 (0) mass 2 (6) 12 (28) 12 (32) 15 (54) lung white zone 2 (6) 0 (0) 0 (0) 1 (4) red zone 0 (0) 0 (0) 1 (3) 0 (0) nodule 5 (16) 2 (5) 1 (3) 1 (4) lymph node enlarged 0 (0) 1 (2) 1 (3) 1 (4) spleen enlarged 2 (6) 2 (5) 4 (11) 2 (7) white zone 0 (0) 0 (0) 1 (3) 0 (0) nodule 0 (0) 1 (2) 1 (3) 1 (4) deformed 1 (3) 0 (0) 1 (3) 4 (14) heart white zone 0 (0) 0 (0) 2 (5) 0 (0) tongue nodule 0 (0) 1 (2) 0 (0) 0 (0) forestomach nodute 1 (3) 0 (0) 0 (0) 0 (0) large intes nodule 0 (0) 0 (0) 0 (0) 1 (4) liver white zone 0 (0) 0 (0) 1 (3) 1 (4) brown zone 1 (3) 0 (0) 0 (0) 0 (0) nodule 1 (3) 0 (0) 2 (5) 2 (7) rough 0 (0) 0 (0) 0 (0) 1 (4) herniation 0 (0) 1 (2) 1 (3) 3 (11) pancreas nodule 1 (3) 1 (2) 0 (0) 1 (4)

0 (0)

0 (0)

1 (3)

kidney

white zone

0 (0)

ANIMAL : RAT F344/DuCrj

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (105W)

REPORT TYPE : A1 SEX : MALE

gan	Findings	Group Name NO. of Animals	Control 32 (%)	1000 ppm 43 (%)	2000 ppm 38 (%)	4000 ppm 28 (%)
idney	cyst		0 (0)	0 (0)	1 (3)	0 (0)
	granular		31 (97)	38 (88)	27 (71)	26 (93)
	nodular		1 (3)	0 (0)	0 (0)	0 (0)
in bladd	urine:marked retention		0 (0)	1 (2)	0 (0)	0 (0)
tuitary	enlarged		1 (3)	0 (0)	2 (5)	3 (11)
	red zane		1 (3)	1 (2)	0 (0)	0 (0)
	nodule		6 (19)	5 (12)	4 (11)	4 (14)
vroid	enlarged		2 (6)	1 (2)	2 (5)	1 (4)
	nodule		3 (9)	0 (0)	1 (3)	3 (11)
renal	enlarged		0 (0)	0 (0)	1 (3)	0 (0)
stis	atrophic		0 (0)	0 (0)	0 (0)	1 (4)
	nodule		30 (94)	43 (100)	38 (100)	26 (93)
re	white		2 (6)	1 (2)	3 (8)	0 (0)
	exophthalmos		0 (0)	0 (0)	1 (3)	0 (0)
eritoneum	nodule		1 (3)	0 (0)	0 (0)	4 (14)
etroperit	cyst		0 (0)	0 (0)	1 (3)	0 (0)
odominal c	red		0 (0)	0 (0)	0 (0)	1 (4)
	ascites		1 (3)	0 (0)	0 (0)	3 (11)
oracic ca	pleural fluid		0 (0)	1 (2)	2 (5)	0 (0)
her:	tail:nodule		0 (0)	1 (2)	0 (0)	0 (0)
	ear:nndule		1 (3)	0 (0)	2 (5)	0 (0)

APPENDIX G4

GROSS FINDINGS: SUMMARY, RAT: FEMALE: ALL ANIMALS

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE GROSS FINDINGS (SUMMARY) ALL ANIMALS (0-105W)

gan		roup Name Control O. of Animals 50 (%)	1000 ppm 50 (%)	2000 ppm 50 (%)	4000 ppm 50 (%)
in/app	nodule	1 (2)	0 (0)	1 (2)	0 (0)
	mass	0 (0)	0 (0)	0 (0)	1 (2)
cutis	jaundice	0 (0)	1 (2)	1 (2)	1 (2)
	mass	10 (20)	12 (24)	10 (20)	15 (30)
g	white zone	0 (0)	0 (0)	1 (2)	0 (0)
	nodule	3 (6)	1 (2)	1 (2)	2 (4)
iph node	enlarged	0 (0)	2 (4)	2 (4)	1 (2)
mus	entarged	0 (0)	0 (0)	1 (2)	0 (0)
een	enlarged	0 (0)	6 (12)	6 (12)	6 (12)
	nodute	0 (0)	0 (0)	1 (2)	0 (0)
rt	red zone	0 (0)	1 (2)	0 (0)	1 (2)
	di lated	0 (0)	0 (0)	0 (0)	1 (2)
estomach	ulcer	2 (4)	0 (0)	0 (0)	1 (2)
stomach	ulcer	1 (2)	0 (0)	0 (0)	1 (2)
ll intes	nodule	0 (0)	0 (0)	1 (2)	1 (2)
ge intes	nodule	0 (0)	1 (2)	0 (0)	0 (0)
er	enlarged	0 (0)	0 (0)	1 (2)	1 (2)
	pale	0 (0)	1 (2)	0 (0)	1 (2)
	red	0 (0)	0 (0)	0 (0)	1 (2)
	white zone	0 (0)	2 (4)	0 (0)	1 (2)
	red zone	0 (0)	0 (0)	0 (0)	4 (8)
	brown zone	0 (0)	0 (0)	0 (0)	1 (2)

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : FEMALE

gan	Findings	Group Name NO. of Animals	Control 50 (%)	1000 ppm 50 (%)	2000 ppm 50 (%)	4000 ppm 50 (%)
uer	nodule		1 (2)	3 (6)	2 (4)	4 (8)
	rough		0 (0)	2 (4)	1 (2)	6 (12)
	granular		0 (0)	0 (0)	1 (2)	0 (0)
	nodular		0 (0)	0 (0)	0 (0)	1 (2)
	herniation		2 (4)	4 (8)	2 (4)	0 (0)
ncreas	nodute		1 (2)	0 (0)	0 (0)	1 (2)
dney	pale		0 (0)	1 (2)	0 (0)	0 (0)
	white zone		0 (0)	0 (0)	0 (0)	1 (2)
	cyst	•	1 (2)	0 (0)	0 (0)	0 (0)
	granular		11 (22)	1 (2)	7 (14)	6 (12)
	nodular		1 (2)	0 (0)	0 (0)	0 (0)
	hydronephrasis		0 (0)	0 (0)	1 (2)	0 (0)
in bladd	enlarged		0 (0)	0 (0)	0 (0)	1 (2)
	urine:marked retention		0 (0)	0 (0)	0 (0)	1 (2)
tuitary	enlarged		9 (18)	11 (22)	8 (16)	5 (10)
	red		1 (2)	0 (0)	0 (0)	0 (0)
	red zone		5 (10)	7 (14)	4 (8)	6 (12)
	nodule		4 (8)	8 (16)	11 (22)	6 (12)
	cyst		0 (0)	1 (2)	0 (0)	0 (0)
roid	enlarged		2 (4)	1 (2)	0 (0)	3 (6)
	nodule		2 (4)	0 (0)	0 (0)	0 (0)
rathyroid	nadule		0 (0)	0 (0)	1 (2)	0 (0)

STUDY NO. : 0278 ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE GROSS FINDINGS (SUMMARY) ALL ANIMALS (0-105W)

gan	Findings	Group Name NO. of Animals	Control 50 (%)	1000 ppm 50 (%)	2000 ppm 50 (%)	4000 ppm 50 (%)
ary	enlarged		0 (0)	0 (0)	0 (0)	2 (4)
	cyst		1 (2)	3 (6)	0 (0)	0 (0)
erus	black zone		1 (2)	0 (0)	0 (0)	0 (0)
	nodule		3 (6)	2 (4)	4 (8)	9 (18)
	mass		0 (0)	2 (4)	0 (0)	0 (0)
	cyst		0 (0)	2 (4)	0 (0)	3 (6)
ain	red zone		0 (0)	0 (0)	1 (2)	0 (0)
	hemorrhage		0 (0)	1 (2)	0 (0)	0 (0)
nal cord	nodule		0 (0)	0 (0)	1 (2)	0 (0)
	turbid		0 (0)	1 (2)	0 (0)	0 (0)
	white		1 (2)	4 (8)	1 (2)	0 (0)
	deformed		0 (0)	0 (0)	1 (2)	0 (0)
bal gl	nodule		0 (0)	1 (2)	0 (0)	0 (0)
cle	nodule		0 (0)	1 (2)	0 (0)	0 (0)
itoneum	hemorrhage		0 (0)	0 (0)	0 (0)	1 (2)
	nadule		0 (0)	0 (0)	0 (0)	1 (2)
iominal c	hemorrhage		0 (0)	0 (0)	1 (2)	1 (2)
	ascites		0 (0)	0 (0)	0 (0)	4 (8)
pose	nadule		0 (0)	0 (0)	0 (0)	1 (2)
racic ca	pleural fluid		1 (2)	0 (0)	1 (2)	4 (8)
ner	eye lid:nodule		1 (2)	0 (0)	0 (0)	1 (2)
	ear:nodule		0 (0)	0 (0)	1 (2)	0 (0)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

SEX : FEMALE

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

PAGE: 8

Organ	Findings	Group Name NO. of Animals	Control 50 (%)	1000 ppm 50 (%)	2000 ppm 50 (%)	4000 ppm 50 (%)
other	lower jaw:nodule		1 (2)	0 (0)	0 (0)	0 (0)
whole body	anemic		0 (0)	0 (0).	0 (0)	2 (4)

BAIS3

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APPENDIX G 5

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

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

Group Name Contral 1000 ppm 2000 ppm 4000 ppm Findings_ NO. of Animals Organ_ 5 (%) 10 (%) 7 (%) 20 (%) subcutis jaundice 0 (0) 1 (10) 1 (14) 1 (5) mass 0 (0) 2 (20) 0 (0) 1 (5) lung white zone 0 (0) 0 (0) 1 (14) 0 (0) 0 (0) nodule 0 (0) 0 (0) 2 (10) Lymph node enlarged 0 (0) 2 (20) 1 (14) 1 (5) thymus entarged 0 (0) 0 (0) 1 (14) 0 (0) spleen enlarged 0 (0) 4 (40) 4 (57) 4 (20) heart red zone 0 (0) 1 (10) 0 (0) 1 (5) di lated 0 (0) 0 (0) 0 (0) 1 (5) forestomach ulcer 2 (40) 0 (0) 0 (0) 1 (5) gl stomach ulcer 1 (20) 0 (0) 0 (0) 1 (5) small intes nodule 0 (0) 0 (0) 0 (0) 1 (5) large intes nodute 0 (0) 1 (10) 0 (0) 0 (0) Liver enlarged 0 (0) 0 (0) 1 (14) 1 (5) pale 0 (0) 1 (10) 0 (0) 1 (5) red 0 (0) 0 (0) 0 (0) 1 (5) red zone 0 (0) 0 (0) 0 (0) 1 (5) nodule 1 (20) 1 (10) 0 (0) 3 (15) rough 0 (0) 1 (10) 0 (0) 3 (15) granular 0 (0) 0 (0) 1 (14) 0 (0)

0 (0)

0 (0)

0 (0)

1 (10)

0 (0)

0 (0)

nudular

herniation

1 (5)

0 (0)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

gan	Findings	Group Name Control NO. of Animals 5 (%)	1000 ppm 10 (%)	2000 ppm 7 (%)	4000 ppm 20 (%)
ncreas	nadule	0 (0)	0 (0)	0 (0)	1 (5)
queà	white zone	0 (0)	0 (0)	0 (0)	1 (5)
	granular	0 (0)	0 (0)	0 (0)	1 (5)
in bladd	enlarged	0 (0)	0 (0)	0 (0)	1 (5)
	urine:marked retention	0 (0)	0 (0)	0 (0)	1 (5)
tui tary	enlarged	2 (40)	6 (60)	1 (14)	4 (20)
	red zone	0 (0)	0 (0)	0 (0)	3 (15)
	nodule	0 (0)	1 (10)	1 (14)	2 (10)
yroid	enlarged	0 (0)	0 (0)	0 (0)	2 (10)
ary	enlarged	0 (0)	0 (0)	0 (0)	2 (10)
	cyst	0 (0)	1 (10)	0 (0)	0 (0)
erus	nodule	1 (20)	0 (0)	0 (0)	6 (30)
	mass	0 (0)	1 (10)	0 (0)	0 (0)
ain	red zone	0 (0)	0 (0)	1 (14)	0 (0)
	hemorrhage	0 (0)	1 (10)	0 (0)	0 (0)
inal cord	nadule	0 (0)	0 (0)	1 (14)	0 (0)
re	turbid	0 (0)	1 (10)	0 (0)	0 (0)
	white	0 (0)	1 (10)	0 (0)	0 (0)
mbal gi	nodute	0 (0)	1 (10)	0 (0)	0 (0)
ritoneum	hemorrhage	0 (0)	0 (0)	0 (0)	1 (5)
	nadule	0 (0)	0 (0)	0 (0)	1 (5)
dominal c	hemorrhage	0 (0)	0 (0)	1 (14)	1 (5)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

GROSS FINDINGS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

SEX : FEMALE

Organ	Findings	Group Name NO. of Animals	Control 5 (%)	1000 ppm 10 (%)	2000 ppm 7 (%)	4000 ppm 20 (%)
abdominal c	ascites		0 (0)	0 (0)	0 (0)	4 (20)
horacic ca	pleural fluid		1 (20)	0 (0)	1 (14)	4 (20)
her	lower jaw:nodule		1 (20)	0 (0)	0 (0)	0 (0)
nole body	anemic		0 (0)	0 (0)	0 (0)	2 (10)

BAIS 3

APPENDIX G6

GROSS FINDINGS: SUMMARY, RAT : FEMALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

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

Organ	Findings	Group Name NO. of Animals	Contral 45 (%)	1000 ppm 40 (%)	2000 ppm 43 (%)	4000 ppm 30 (%)
skin/app	nodule		1 (2)	0 (0)	1 (2)	0 (0)
	mass		0 (0)	0 (0)	0 (0)	1 (3)
subcutis	mass		10 (22)	10 (25)	10 (23)	14 (47)
lung	nodule		3 (7)	1 (3)	1 (2)	0 (0)
Lymph nade	enlarged		0 (0)	0 (0)	1 (2)	0 (0)
spleen	enlarged		0 (0)	2 (5)	2 (5)	2 (7)
	nodule		0 (0)	0 (0)	1 (2)	0 (0)
small intes	nodule		0 (0)	0 (0)	1 (2)	0 (0)
iver	white zone		0 (0)	2 (5)	0 (0)	1 (3)
	red zone		0 (0)	0 (0)	0 (0)	3 (10)
	brown zone		0 (0)	0 (0)	0 (0)	1 (3)
	nodule		0 (0)	2 (5)	2 (5)	1 (3)
	rough		0 (0)	1 (3)	1 (2)	3 (10)
	herniation		2 (4)	3 (8)	2 (5)	0 (0)
ancreas	nodule		1 (2)	0 (0)	0 (0)	0 (0)
idney	pale		0 (0)	1 (3)	0 (0)	0 (0)
	cyst		1 (2)	0 (0)	0 (0)	0 (0)
	granular		11 (24)	1 (3)	7 (16)	5 (17)
	nodular		1 (2)	0 (0)	0 (0)	0 (0)
	hydronephrosis		0 (0)	0 (0)	1 (2)	0 (0)
iturtary	enlarged		7 (16)	5 (13)	7 (16)	1 (3)
	red		1 (2)	0 (0)	0 (0)	0 (0)

STUDY NO. : 0278 ANIMAL : RAT F344/DuCrj

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

PAGE: 4

Organ	Findings	Group Name NO. of Animals	Control 45 (%)	1000 ppm 40 (%)	2000 ppm 43 (%)	4000 ppm 30 (%)
pituitary	red zone		5 (11)	7 (18)	4 (9)	3 (10)
	nodule		4 (9)	7 (18)	10 (23)	4 (13)
	cyst		0 (0)	1 (3)	0 (0)	0 (0)
nyroid	enlarged		2 (4)	1 (3)	0 (0)	1 (3)
	nodule		2 (4)	0 (0)	0 (0)	0 (0)
rathyroid	nodule		0 (0)	0 (0)	1 (2)	0 (0)
ary	cyst		1 (2)	2 (5)	0 (0)	0 (0)
erus	black zone		1 (2)	0 (0)	0 (0)	0 (0)
	nodule		2 (4)	2 (5)	4 (9)	3 (10)
	mass		0 (0)	1 (3)	0 (0)	0 (0)
	cyst		0 (0)	2 (5)	0 (0)	3 (10)
е	white		1 (2)	3 (8)	1 (2)	0 (0)
	deformed		0 (0)	0 (0)	1 (2)	0 (0)
scle	nodule		0 (0)	1 (3)	0 (0)	0 (0)
ipose	nodule		0 (0)	0 (0)	0 (0)	1 (3)
her	eye lid:nadule		1 (2)	0 (0)	0 (0)	1 (3)
	ear:nodule		0 (0)	0 (0)	1 (2)	0 (0)

(HPT080)

APPENDIX H 1

ORGAN WEIGHT , ABSOLUTE: SUMMARY, RAT: MALE

(2-YEAR STUDY)

STUDY NO. : 0278 ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : MALE UNIT: g

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

PAGE: 1

Group Name	NO. of Animals	Body Weig	eht	ADRENAL	.S	TEST	ES	HEART	[LUNG	5	KIDNI	EYS
Control	32	383± 36	8 0.0	81± 0	0.009	5.771±	1.757	1.240±	0.098	1.515±	0.171	3.023±	0.334
1000 ppm	43	408± 3	6 0.0	81± 0	0.015	5,961±	1.526	1.288±	0.106	1.503±	0.194	2.906±	0.257
mqq 000	38	392± 4	0 0.1	14± 0	0.201	6.742±	2.186	1.271±	0.114	1.597±	0.452	2.960±	0.388
1000 ppm	28	399± 6	0.0	86± 0	0.024	6.553±	2.391	1.276±	0.107	1.528±	0.314	2.891±	0.231

(HCL040)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

SEX : MALE UNIT: g

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

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN	
Control	32	1.253± 0.503	12.992± 1.665	2.038± 0.033	
1000 ppm	43	1.351± 0.870	12.112± 1.557	2.030 ± 0.044	
2000 ppm	38	1.669± 1.422	12.514± 1.630	2.013± 0.045	
4000 ppm	28	1.321± 0.855	13.515± 1.719	2.022± 0.045	
Significan	t difference ;	*:P≦0.05 **	: P ≤ 0.01	Test of Dunnett	

(IICL040)

BAIS3

APPENDIX H 2

ORGAN WEIGHT , ABSOLUTE: SUMMARY, RAT: FEMALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

PAGE: 3

Group Name	NO. of Animals	Body	Weight	ADRE	NALS	OVAR	IES	HEAR	[LUNG	S	KIDNI	EYS
Control	45	295±	30	0.080±	0.012	0.140±	0.128	0.949±	0.065	1.064±	0.075	2.063±	0.173
1000 ppm	40	293±	32	0.081±	0.012	0.151±	0.202	0.992±	0.087*	1.110±	0.188	2.014±	0.172
mqq 0008	43	295±	25	0.081±	0.013	0.113±	0.022	0.996±	0.078*	1.134±	0.250	2.099±	0.287
4000 ppm	30	281±	31	0.080±	0.010	0.123±	0.024	0.995±	0.084*	1.104±	0.150	2.040±	0.194

(HCL040)

ANIMAL : RAT F344/DuC-j REPORT TYPE : A1

SEX : FEMALE UNIT: g

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

					PAGE:
roup Name	NO. of Animals	SPLEEN	LIVER	BRAIN	
Control	45	0.582± 0.201	7.864± 1.393	1.836± 0.043	
1000 ppm	40	0.804± 0.929	8.773± 1.069**	1.853± 0.039	
2000 ppm	43	1.196± 2.588	9.852± 1.371**	1.840± 0.055	
4000 ppm	30	1.074± 1.596*	9.941± 2.078**	1.834± 0.051	
Significan	t difference ;	*: P ≤ 0.05	**: P ≤ 0.01	Test of Dunnett	

BAISS

APPENDIX I1

ORGAN WEIGHT, RELATIVE: SUMMARY, RAT: MALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE UNIT: %

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

PAGE: 1

Group Name	NO. of Animals	Body Weight (g)	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS	
Control	32	383± 38	0.021± 0.004	1.508± 0.456	0.327± 0.045	0.398± 0.051	0.797± 0.132	
1000 ppm	43	408± 36	0.020± 0.005	1.461± 0.365	0.317± 0.032	0.370± 0.050**	0.719± 0.108	
2000 ppm	38	392± 40	0.029± 0.049	1.714± 0.547	0.327± 0.041	0.415± 0.147	0.766± 0.150	
4000 ppm	28	399± 60	0.021± 0.004	1.673± 0.652	0.324± 0.037	0.392± 0.131	0.739± 0.127	

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

SEX : MALE UNIT: %

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

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	32	0.325± 0.120	3.407± 0.449	0.537± 0.061
1000 ppm	43	0.334± 0.224	2.981± 0.383**	0.501± 0.044*
2000 ppm	38	0.440± 0.440	3.222± 0.545	0.519± 0.060
4000 ppm	28	0.324± 0.164	3.443± 0.657	0.517± 0.074
Significan	nt difference;	*: P ≤ 0.05 **:	P ≤ 0.01	Test o

(HCL042)

BAIS3

APPENDIX I 2

ORGAN WEIGHT, RELATIVE: SUMMARY, RAT: FEMALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE UNIT: %

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

PAGE: 3

Group Name	NO. of Animals	Body Weight (g)	ADRENALS	OVARIES	HEART	LUNGS	KIDNEYS
Control	45	295± 30	0.027± 0.004	0.046± 0.033	0.324± 0.028	0.364± 0.038	0.707± 0.091
1000 ppm	40	293± 32	0.028± 0.006	0.055± 0.092	0.343± 0.057	0.384± 0.088	0.697± 0.121
2000 ppm	43	295± 25	0.028± 0.005	0.038± 0.007	0.339± 0.035	0.386± 0.089	0.718± 0.150
4000 ppm	30	281± 31	0.029± 0.004	0.044± 0.008	0.357± 0.031**	0.398± 0.069	0.731 ± 0.062

(IICL042)

STUDY NO. : 0278 ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : FEMALE UNIT: %

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

PAGE: 4

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN	
Control	45	0.198± 0.066	2.674± 0.390	0.629± 0.061	
1000 ppm	40	0.277± 0.314	3.017± 0.464**	0.640± 0.075	
2000 ppm	43	0.411± 0.917	3.341± 0.438**	0.627± 0.053	
4000 ppm	30	0.388± 0.597**	3.523± 0.453**	0.661± 0.075	

(IICL042)

APPENDIX J1

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY, RAT: MALE: ALL ANIMALS (2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : MALE

0rgan	No	oup Name Control . of Animals on Study 50 ade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
[Integumentar	ry system/appandage]				
skin/app	hyperplasia:epidermis	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)
	scab	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)	0 1 0 0 (0) (2) (0) (0)
	epidermal cyst	0 0 0 0 0 (0) (0)	0 2 0 0 (0) (4) (0) (0)	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 (0)
subcutis	cyst	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)
	abscess	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0)	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 (0)
[Respiratory	system]				
nasal cauit	thrombus	50> 5 0 0 0 (10) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	<50> 4 0 0 0 (8) (0) (0) (0)	(50) 4 0 0 0 (8) (0) (0) (0)
Grade (a) b (c) Significant d	1: Slight 2: Moderate 3: a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 lifference; $*: P \le 0.05$ **: $P \le 0$				

(IIPT150)

BAIS3

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1 SEX

: MALE

PAGE: 2

Organ	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
Respiratory	system]				
nasal cavit	mineralization	30 0 0 0 (60)(0)(0)(0)	(50) 40 0 0 0 * (80) (0) (0) (0)	(50) 40 0 0 0 * (80) (0) (0) (0)	<pre></pre>
	inflammatory infiltration	0 0 0 0 0 0 (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)
	easinophilic change:olfactory epithel	35 5 3 0 (70) (10) (6) (0)	27 17 3 0 * (54) (34) (6) (0)	28 18 3 0 ** (56) (36) (6) (0)	33 10 5 0 (66) (20) (10) (0)
	easinophilic change:respiratory epith	elium 6 0 0 0 (12) (0) (0) (0)	1 0 0 0 0 (2) (0) (0)	3 0 0 0 0 (6) (6) (0) (0)	12 0 0 0 (24) (0) (0) (0)
	inflammation:foreign body	21 2 0 0 (42) (4) (0) (0)	13 3 0 0 (26) (6) (0) (0)	12 0 0 0 * (24) (0) (0) (0)	15 0 0 0 (30) (0) (0) (0)
	inflammation:respiratory epithelium	1 0 0 0 (2) (0) (0) (0)	1 0 0 0 0 (2) (0) (0)	3 1 0 0 (6) (2) (0) (0)	0 0 0 0 0 (0) (0)
	inflammation:olfactory epithelium	0 0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)
	respiratory metaplasia:olfactory epit	15 6 1 0 (30) (12) (2) (0)	11 1 0 0 (22) (2) (0) (0)	17 0 0 0 (34) (0) (0) (0)	7 1 0 0 * (14) (2) (0) (0)

(c) (HPT150)

b

b: Number of animals with lesion

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

c:b/a*100

ANIMAL : RAT F344/DuCrj

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1 SEX : MALE

Group Name Control 1000 ppm 2000 ppm 4000 ppm No. of Animals on Study 50 50 50 50 Findings (%) (%) [Respiratory system] nasal cavit <50> <50> <50> respiratory metaplasia:gland 0 0 0 0 0 0 0 (92) (0) (0) (0) (94) (0) (0) (0) (88) (0) (0) (0) (80) (0) (0) (0) atrophy:olfactory epithelium 0 0 0 ** 0 ** (22) (0) (0) (0) (2)(0)(0)(0) (0)(0)(0)(0) (8)(0)(0)(0) erosion:olfactory epithelium 0 0 0 0 0 0 0 0 (0)(0)(0)(0) (2)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) thickening of bone:turbinate 6 0 0 0 0 (12) (0) (0) (0) (6)(0)(0)(0) (4)(0)(0)(0) (8) (0) (0) (0) nasopharynx <50> <50> <50> <50> easinophilic change 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) inflammation (6)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) larynx <50> <50> <50> mineralization 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 * 100Significant difference; *: $P \le 0.05$ **: $P \le 0.01$ Test of Chi Square

(HPT150)

BAIS3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : MALE

ALL ANIMALS (0-105W)

Organ		Group Name Contro No. of Animals on Study 50 Grade 1 2 (%) (%)		1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
(Respirator)	v system]					
larynx	inflammation	0 0 (0) (0) (0 0	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)
lung	cangestian	0 1 (0) (2) (0 0	(50) 2 0 0 0 (4) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)
	foreign body granuloma	0 1 (0) (2)	0 0	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)
	osseous metaplasia	1 0 (2) (0)	0 0	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)
	interstitial penumonia	23 6 (46) (12)	0 0	36 2 0 0 * (72) (4) (0) (0)	32 7 3 0 * (64) (14) (6) (0)	20 3 0 0 (40) (6) (0) (0)
	bronchiolar-alveolar cell hyperplasia	3 0 (6) (0)	0 0 (0) (0)	3 0 0 0 0 (6) (6) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)
	mineralization:artery	0 1 (0) (2)	0 0 (0) (0)	2 0 0 0 0 (4) (0) (0) (0)	3 0 0 0 0 (6) (6) (0) (0)	1 0 0 0 (2) (0) (0) (0)
	endothelial cell hyperplasia	0 0	0 0	1 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0) (0)

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

b

c:b/a * 100 (c)

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

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1 SEX : MALE

PAGE: 5

Organ		or Name Control of Animals on Study 50 or 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
[Hematopoietio	c system]				
bone marrow	granulation	<50> 1 0 0 0 (2) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	<50> 0 0 0 0 (0) (0) (0) (0)
	increased hematopolesis	18 0 0 0 (36) (0) (0) (0)	20 0 0 0 0 (40) (0) (0)	15 0 0 0 (30) (0) (0) (0)	27 0 0 0 (54) (0) (0) (0)
	erythropoiesis:increased	1 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (2) (0) (0)	1 0 0 0 0 (2) (0) (0)
lymph nade	lymphadenitis	<50> 2 0 0 0 (4) (0) (0) (0)	<50> 2 0 0 0 (4) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)
	follicular hyperplasia	1 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0)
spleen	ectopic tissue	<50> 0 0 1 0 (0) (0) (2) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
	congestion	13 4 0 0 (26) (8) (0) (0)	3 1 0 0 ** (6) (2) (0) (0)	2 0 0 0 *** (4) (0) (0) (0)	11 1 0 0 (22) (2) (0) (0)
Grade <a>> b (c) Significant d	1: Slight 2: Moderate 3: Man a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 lifference; $*: P \le 0.05$ **: $P \le 0.0$			•	

(HPT150)

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1 : MALE SEX

0rgan	No	roup Name Control o. of Animals on Study 50 rade <u>1 2 3 4</u> (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
[Hematopoie	etic system]				
spleen	karyorrhexis	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)	<pre></pre>	(50) 0 0 0 0 (0) (0) (0) (0)
	deposit of hemosiderin	6 2 0 0 (12) (4) (0) (0)	7 1 0 0 (14) (2) (0) (0)	9 2 0 0 (18) (4) (0) (0)	8 3 2 0 (16) (6) (4) (0)
	fibrosis	1 0 0 0 0 (2) (0) (0) (0)	1 1 0 0 (2) (2) (0) (0)	3 2 0 0 (6) (4) (0) (0)	6 5 0 0 * (12) (10) (0) (0)
	extramedullary hematopoiesis	2 2 1 0 (4) (4) (2) (0)	2 1 1 0 (4) (2) (2) (0)	6 2 0 0 (12) (4) (0) (0)	4 2 6 0 (8) (4) (12) (0)
	splenitis	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)
	stromal hyperplasia	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)
[Circulator	ry system]				
neart	thrombus	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 1 0 (0) (0) (2) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 1 0 (2) (0) (2) (0)
Grade (a > b (c) Significant	1 : Slight 2 : Moderate 3 : a : Number of animals examined at the site b : Number of animals with lesion c : b / a * 100 t difference; * : P ≤ 0.05 ** : P ≤ 0				

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1 : MALE SEX

Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
tem]				
necrosis:focal	(50) 1 0 0 0 (2) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)
mineralization	1 0 0 0 0 (2) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (0)
myocardial fibrosis	4 2 0 0 (8) (4) (0) (0)	16 0 0 0 *** (32) (0) (0) (0)	20 0 0 0 *** (40) (0) (0) (0)	7 1 0 0 (14) (2) (0) (0)
mineralization	(50) 0	(50) 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 1 0 (0)(0)(2)(0)
arteritis	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	0 2 0 0 (0) (4) (0) (0)
periarteritis nodosa	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
m]				
dysplasia	(50) 9 5 0 1 (18) (10) (0) (2)	(50) 14 2 0 0 (28) (4) (0) (0)	(50) 7 6 0 0 (14) (12) (0) (0)	(50) 17 3 0 0 (34) (6) (0) (0)
	Findings	Findines Grade 1 2 3 4 (%) (%) (%) (%) (%) (%) (%) (%) (%) (%)	Findings Grade 1 2 3 4 1 2 3 4 (%) (%) (%) (%) (%) (%) (%) (%) (%) (%)	Findings Grade 1 2 3 4 1 2 3 4 1 2 3 4 1 2 3 4 (%) (%) (%) (%) (%) (%) (%) (%) (%) (%)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY) ALL ANIMALS (0-105W)

PAGE: 8

)rgan		No. of Animals on Study Grade 1	ntrol 50 2 3 %) (%)	<u>4</u> (%)	1	00 ppm 50 2 3 (%) (%)	<u>4</u> (%)	1(%)	2000 pp 50 2 (%)		<u>4</u> (%)	<u>(</u> :	1	00 ppn 50 2 (%)		<u>4</u> (%)
Digestive sy	rstem]															
tangue	mineralization		<50> 0 1 0) (2) (0 (0) (<50> 0 0 0) (0)		1 (2)	<50 0 (0)	0	0 (0)	(2 4) (<50) 0 0) () 1 2) (0 (0)
	abscess	(0) (0 0 0) (0) (0 0)	(0) (1 0 2) (0)	0 (0)	0 (0)	0 (0)	0 (0) (0 (0)	(0 0) (0 (0	0
	arteritis		0 0 0) (0) (0	1 (2) (0 0	0 (0)	1 (2)	0 (0)	0 (0) (0 (0)	(2 4) (0 (0	0
sophagus	C-cell hyperplasia		<50> 0 0 0) (0) (0 0)	0 (0) (<50> 0 0 0) (0)	0 (0)	1 (2)	<50 0 (0) :)> 0 (0) (0 ()	()	0 0) (<50> 0 0) () 0 0) (0
	focal follicular cell hyperplasia		0 0	0 0)	(0) (0 0	0 (0)	1 (2)	0 (0) (0 (0) (0 (0)	()	0 0) (0 (0	0 0)
tomach	mineralization		<50> 0 1 0) (2) (0 0)	0 (0) (<50> 0 0 0) (0)	0 (0)	0 (0)	<5(0 (0) (0	0 0)	()	0 0) (<50> 0 0) () 1 2) (0
	inflammatory infiltration	2 (4) (0) (0) (0 0)	0 (0) (0 0	0 (0)	0 (0)	0 (0) (0 (0) (0 0)	()	0 0) (0 (0	0 (0)
rade a > b c) ignificant d	1: Slight 2: Moderate 3 a: Number of animals examined at the si b: Number of animals with lesion c: b / a * 100 lifference; *: P ≤ 0.05 **: P ≤															

(HPT150)

SEX

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj

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

PAGE: 9 Group Name Control 1000 ppm 2000 ppm 4000 ppm No. of Animals on Study 50 50 50 50 0rgan Findings_ [Digestive system] stomach <50> ⟨50⟩ <50> periarteritis nodosa 0 0 0 1 0 0 0 (0)(0)(0)(0) (0)(0)(2)(0) (0)(0)(0)(0) (0)(0)(0)(0) ulcer:forestomach 0 1 0 2 0 3 1 0 (0)(4)(6)(0) (0)(0)(2)(0) (0)(2)(0)(4) (0)(6)(2)(0) hyperplasia: forestomach 0 4 0 1 0 1 0 1 2 1 0 3 0 0 0 (2)(0)(8)(0) (2) (0) (2) (0) (2)(4)(2)(0) (6)(0)(0)(0) erosion:glandular stomach 3 0 0 0 0 0 0 2 (6)(0)(0)(0) (2)(0)(0)(0) (0)(0)(0)(0) (4)(2)(0)(0) ulcer:glandular stomach 0 0 0 0 0 1 (0)(4)(0)(0) (0)(0)(0)(0) (0) (0) (0) (0) (0)(2)(0)(0) small intes ⟨50⟩ <50> <50> ⟨50⟩ periarteritis nodosa 0 0 0 0 1 0 0 0 0 0 (0)(0)(0)(0) (0)(0)(2)(0) (0)(0)(0)(0) (0)(0)(0)(0) large intes <50> <50> <50> <50> mineralization 0 0 0 0 0 0 0 0 0 0 0 0 0 (2)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe <a>> a: Number of animals examined at the site b b: Number of animals with lesion (c) c:b/a*100

(HPT150)

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

STUDY NO. : 0278 ANIMAL : RAT F344/DuCrj HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

REPORT TYPE : A1

SEX : MALE

ALL ANIMALS (0-105W)

Organ	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
[Digestive sys	stem]				
large intes	inflammation	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)
liver	herniation	\(\frac{50}{2} \) (2) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	<pre></pre>	<50> 3 0 0 0 (6) (0) (0) (0)
	peliosis-like lesion	2 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	necrosis:central	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	3 0 0 0 (6) (6) (7) (7)
	necrosis:focal	1 0 0 0 0 (2) (2) (3) (4)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 2 0 0 (0) (4) (0) (0)
	fatty change	0 0 2 0 (0) (4) (0)	1 0 0 0 (2) (0) (0) (0)	10 0 0 0 *** (20) (0) (0) (0)	5 0 0 0 * (10) (0) (0) (0)
	fatty chango:central	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)	1 0 2 0 (2) (0) (4) (0)	0 1 1 0 (0) (2) (2) (0)
	fatty change:peripheral	2 1 1 0 (4) (2) (2) (0)	4 9 0 0 * (8) (18) (0) (0)	6 0 0 0 (12) (0) (0) (0)	2 0 0 0 (4) (0) (0) (0)

4 : Severe

(a)

a: Number of animals examined at the site

b

b: Number of animals with lesion

c:b/a*100 (c)

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

(HPT150)

BAIS3

^{3 :} Marked

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : MALE

ALL ANIMALS (0-105W)

)rgan	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
Digestive	system]				
iver.	granulation	(50) 6 0 0 0 (12) (0) (0) (0)	5 0 0 0 (10) (0) (0)	\$ 0 0 0 (16) (0) (0) (0)	3 0 0 0 (6) (0) (0) (0)
	perivascular inflammation	0 1 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)
	clear cell focus	2 0 0 0 (4) (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	1 1 0 0 (2) (2) (0) (0)
	acidophilic cell focus	17 5 0 0 (34) (10) (0) (0)	23 6 2 0 (46) (12) (4) (0)	17 16 0 0 * (34) (32) (0) (0)	13 10 1 0 (26) (20) (2) (0)
	basophilic cell focus	12 1 0 0 (24) (2) (0) (0)	31 5 0 0 ** (62) (10) (0) (0)	20 1 0 0 (40) (2) (0) (0)	11 6 1 0 (22) (12) (2) (0)
	vacuolated cell focus	9 0 0 0 0 (18) (0) (0) (0)	1 0 0 0 * (2) (0) (0) (0)	12 1 0 0 (24) (2) (0) (0)	8 0 0 0 (16) (0) (0) (0)
	spongiosis hepatis	6 0 0 0 (12) (0) (0) (0)	0 0 0 0 *	3 0 0 0 0 (6) (6) (0) (0)	6 0 0 0 0 (12) (0) (0) (0)
	bile duct hyperplasia	24 24 1 0 (48) (48) (2) (0)	35 4 0 0 ** (70) (8) (0) (0)	30 12 0 0 * (60) (24) (0) (0)	27 19 1 0 (54) (38) (2) (0)

(a)

a: Number of animals examined at the site

b

b: Number of animals with lesion

(c)

c:b/a*100

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

(HPT150)

BAIS3

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1 SEX

: MALE

PAGE: 12

Organ		O Name Control of Animals on Study 50 e	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
[Digestive s	ystem]				
Liver	bile ductular proliferation	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 1 1 0 0 (2) (2) (0) (0)
	biliary cyst	2 0 0 0 0 0 (4) (0) (0)	1 0 0 0 0 (2) (3) (4)	2 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 (0) (0)
pancreas	atrophy	<50> 7 1 0 0 (14) (2) (0) (0)	<50> 2 2 0 0 (4) (4) (0) (0)	(50) 9 1 0 0 (18) (2) (0) (0)	<50> 9 0 0 0 (18) (0) (0) (0)
	inflammatory infiltration	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	islet cell hyperplasia	2 0 0 0 0 (4) (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	hyperplasia:acinar cell	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0)	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
[Urinary sys	rtem]				
kidney	thrombus	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)
Grade (a) b (c) Significant	1: Slight 2: Moderate 3: Man a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; *: $P \le 0.05$ **: $P \le 0.0$				

(HPT150)

ANIMAL : RAT F344/DuC-j

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

REPORT TYPE : A1

SEX : MALE

PAGE: 13

Organ	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
[Urinary sys	stem]	•			
kidney	cyst	<50> 0 1 0 0 (0) (2) (0) (0)	(50) 0 0 0 0 (0)(0)(0)(0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)
	hyaline droplet	0 0 1 0 (0) (0) (2) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	basophilic change	16 25 0 0 (32) (50) (0) (0)	28 7 0 0 ** (56) (14) (0) (0)	24 10 0 0 ** (48) (20) (0) (0)	21 8 0 0 ** (42) (16) (0) (0)
•	deposit of hemosiderin	15 0 0 0 (30) (0) (0) (0)	29 0 0 0 ** (58) (0) (0) (0)	32 1 0 0 ** (64) (2) (0) (0)	22 4 0 0 * (44) (8) (0) (0)
	easinophilic bady	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 1 0 0 (0) (2) (0) (0)
	chronic nephropathy	2 4 16 26 (4) (8) (32) (52)	4 10 28 7 ** (8) (20) (56) (14)	5 12 22 11 ** (10) (24) (44) (22)	6 12 17 11 * (12) (24) (34) (22)
	hydronephrosis	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0 (0) (0) (0)
	mineralization:papilla	1 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0) (0)

b

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

(HPT150)

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : MALE

PAGE: 14

Organ	N	roup Name Control o. of Animals on Study 50 rade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
[Urinary sys	tem]				
kidney	mineralization:cortex	<50> 2 0 0 0 (4) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 2 0 0 0 (4) (0) (0) (0)
	urothelial hyperplasia:pelivis	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	2 0 0 0 0 (4) (0) (0) (0)	2 0 0 0 0 (4) (0) (0) (0)
urin bladd	hemorrhagic inflammation	<50> 0 0 0 0 (0) (0) (0) (0)	0 0 1 0 (0) (0) (2) (0)	0 0 0 0 (0) (0) (0) (0)	<49> 0 0 0 1 0 0 0 2
(Endocrine s	ystem]				
pituitary	angiectasis	<50> 0 0 0 0 (0) (0) (0) (0)	\(\lambda 50 \rangle \) \[1 0 0 0 (2) (0) \	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
	cyst	0 0 0 0 0 (0)	4 1 0 0 (8) (2) (0) (0)	5 0 0 0 (10) (0) (0) (0)	5 0 0 0 (10) (0) (0) (0)
	hyperplasia	13 2 0 0 (26) (4) (0) (0)	20 6 2 0 * (40) (12) (4) (0)	11 7 0 0 (22) (14) (0) (0)	17 7 0 0 (34) (14) (0) (0)
Grade <a>> b (c) Significant	1: Slight 2: Moderate 3: a: Number of animals examined at the sit b: Number of animals with lesion c: b/a*100 difference; $*:P \le 0.05$ **: $P \le 0.05$				

(HPT150)

STUDY NO. : 0278 ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

: MALE

PAGE: 15

Organ		Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
[Endocrine s	system]				
pituitary	Rathke pouch	<50> 0 0 0 0 (0) (0) (0) (0)	3 0 0 0 (6) (0) (0) (0)	<50> 2 0 0 0 (4) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
thyroid	ultimibranchial body remanet	<50> 0 0 0 0 (0) (0) (0) (0)	<48> 0 0 0 0 0 0 0 0 0 0 0	<49> 0 0 0 0 0 0 0 0 0 0 0 0	<50> 1 0 0 0 (2) (0) (0) (0)
	adenomatous goiter	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)
	C-cell hyperplasia	9 0 0 0 0 (18) (0) (0) (0)	7 0 0 0 (15) (0) (0) (0)	6 2 0 0 (12) (4) (0) (0)	3 0 0 0 0 (6) (6) (70) (70)
	focal follicular cell hyperplasia	2 1 0 0 (4) (2) (0) (0)	4 0 0 0 0 (8) (0) (0) (0)	2 0 0 0 0 (4) (0) (0) (0)	1 1 0 0 (2) (2) (0) (0)
adrena l	peliosis-like lesion	<50> 4 0 0 0 (8) (0) (0) (0)	50> 5 0 0 0 (10) (0) (0) (0)	<50> 10 0 0 0 (20) (0) (0) (0)	\$50> 9 0 0 0 (18) (0) (0) (0)
	necrosis:focal	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) (0) .
Grade (a) b (c) Significant	1: Slight 2: Moderate 3 a: Number of animals examined at the sib: Number of animals with lesion c:b/a*100 difference; $*:P \le 0.05$ **: $P \le 0.05$				·

(HPT150)

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1
SEX : MALE

Organ	Findings	Group Name Control	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
(Endocrine s	system]				
adrena l	hyperplasia:cortical cell	<50> 2 0 0 0 (4) (0) (0) (0)	\$50\$ 5 1 0 0 (10) (2) (0) (0)	(50) 6 1 0 0 (12) (2) (0) (0)	<50> 6 0 0 0 (12) (0) (0) (0)
	hyperplasia:medulla	8 5 0 0 (16) (10) (0) (0)	17 3 0 0 (34) (6) (0) (0)	20 3 0 0 * (40) (6) (0) (0)	16 6 0 0 (32) (12) (0) (0)
	focal fatty change:cortex	9 1 0 0 (18) (2) (0) (0)	7 2 0 0 (14) (4) (0) (0)	8 5 0 0 (16) (10) (0) (0)	6 4 0 0 (12) (8) (0) (0)
	focal hypertrophy:cortex	2 0 0 0 0 (4) (0) (0) (0)	3 0 0 0 0 (6) (6) (0) (0)	3 1 0 0 (6) (2) (0) (0)	4 1 0 0 (8) (2) (0) (0)
Reproductiv	ue system]				
estis	atrophy	0 1 9 39 (0) (2) (18) (80)	(50) 0 1 1 48 * (0) (2) (2) (96)	(50) 0 2 3 44 (0) (4) (6) (88)	<pre></pre>
	mineralization	2 0 0 0 0 (4) (0) (0) (0)	6 0 0 0 (12) (0) (0) (0)	5 0 0 0 (10) (0) (0) (0)	1 0 0 0 0 (2) (0) (0)
	arteritis	1 0 0 0 0 (2) (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
Grade (a > b (c) Significant	1: Slight 2: Moderate 3 a: Number of animals examined at the s b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤				

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

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : MALE

Organ		Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
[Reproductive	system]				
testis	interstitial cell hyperplasia	3 0 0 0 (6) (0) (0) (0)	3 0 0 0 (6) (0) (0) (0)	<50> 4 0 0 0 (8) (0) (0) (0)	<50> 2 0 0 0 (4) (0) (0) (0)
epididymis	spermatogenic granuloma	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
prostate	inflammation	<50> 5 1 0 0 (10) (2) (0) (0)	<50> 2 0 0 0 (4) (0) (0) (0)	<50> 4 0 0 0 (8) (0) (0) (0)	<50> 3 0 0 0 (6) (0) (0) (0)
mammary gl	duct ectasia	<50>. 3 1 0 0 (6) (2) (0) (0)	<50> 2 0 0 0 (4) (0) (0) (0)	<50> 2 0 0 0 (4) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
	galactocele	2 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)
prep/cli gl	duct ectasia	(50) 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)
(Nervous syst	rem]				
brain	gliosis	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
Grade <a>> b (c) Significant d	a: Number of animals examined at the sib: Number of animals with lesionc: b / a * 100				

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj ALL ANIMALS (0-105W)

REPORT TYPE : A1 : MALE SEX

PAGE: 18

Organ	Findings	Group Name Control	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
(Nervous syste	em]				
spinal cord	gliosis	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)
[Special sense	e organs/appandage]				
еуе	cataract	(50) 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 4 0 0 0 (8) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)
	retinal atrophy	2 0 0 1 (4) (0) (0) (2)	0 0 0 0 0 0 (0) (0)	1 1 2 2 (2) (2) (4) (4)	0 0 0 1 (0) (0) (2)
	keratitis	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	3 0 0 0 0 (6) (6) (0) (0)
	iritis	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)	2 0 0 0 0 (4) (0) (0) (0)
	phthisis bulbi	1 0 0 0 0 (2) (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	2 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 0 (0) (0)
	degeneration:cornea	2 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)
Grade <a>> b (c) Significant d	a: Number of animals examined at the sb: Number of animals with lesionc: b / a * 100				

(HPT150)

STUDY NO. : 0278 ANIMAL : RAT F344/DuC-j

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

REPORT TYPE : A1
SEX : MALE

PAGE: 19

Organ	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%)
(Special ser	nse organs/appandage]				
өуө	mineralization:cornea	33 0 0 0 (66)(0)(0)(0)	<50> 25 0 0 0 (50) (0) (0) (0)	<50> 26 0 0 0 (52) (0) (0) (0)	<50> 17
Harder gl	atrophy	(50) 0 2 0 0 (0) (4) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
	degeneration	22 1 0 0 (44) (2) (0) (0)	26 1 0 0 (52) (2) (0) (0)	25 3 0 0 (50) (6) (0) (0)	16 0 0 0 (32) (0) (0) (0)
	inflammatory infiltration	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0)
nasolacr d	inflammation	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	2 0 0 0 (4) (0) (0) (0)	2 0 0 0 (4) (0) (0) (0)
[Musculoskel	Letal system]				
muscle	mineralization	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 1 1 0 0 (2) (2) (0) (0)	(50) 1 1 0 0 (2) (2) (0) (0)
Grade <a> b (c) Significant	1: Slight 2: Moderate 3 a: Number of animals examined at the s b: Number of animals with lesion c: b / a * 100 difference; $*: P \leq 0.05$ **: $P \leq 0.05$			~	D. MO

(HPT150)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

PAGE: 20

	Group No. of Grade	Animals on Study 50	1000 ppm 50 1 2 3 4	2000 ppm 50 1 2 3 4	4000 ppm 50 1 2 3 4
rgan	Findings	(%) (%) (%)	(%) (%) (%)	(%) (%) (%) (%)	(%) (%) (%) (%)
Musculaske	letal system]				
uscle	inflammation	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) · 1 0 0 0 (2) (0) (0) (0)
	arteritis	0 0 0 0 0 (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
one	asteasclerasis	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 2 0 0 0 (4) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
rade (a > b (c)	1: Slight 2: Moderate 3: Mark a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; *: $P \le 0.05$ **: $P \le 0.01$				
(HPT150)	4. F = 0.01	Test of Gif Square			R

APPENDIX J2

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY, RAT: MALE: DEAD AND MORIBUND ANIMALS (2-YEAR STUDY)

: RAT F344/DuCrj ANIMAL : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

REPORT TYPE : A1

DEAD AND MORIBUND ANIMALS (0-105W)

Group Name Control 1000 ppm 2000 ppm 4000 ppm No. of Animals on Study 18 12 22 Grade (%) Findings_ [Integumentary system/appandage] skin/app <18> < 7> scab 0 0 0 0 0 0 0 0 1 0 0 0 0 0 (0)(0)(0)(0) (0)(0)(0)(0) (0)(8)(0)(0) (0)(0)(0)(0) subcutis <18> < 7> <12> cyst 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)(5)(0)(0) [Respiratory system] nasal cavit <18> < 7> <12> <22> thrombus 5 0 0 0 1 0 0 0 2 0 0 0 (28) (0) (0) (0) (14) (0) (0) (0) (17) (0) (0) (0) (18) (0) (0) (0) mineralization 0 0 0 0 0 10 0 0 0 (50) (0) (0) (0) (57) (0) (0) (0) (83) (0) (0) (0) (41) (5) (0) (0) inflammatory infiltration 0 0 0 0 0 0 0 0 0 0 0 0 (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (5)(0)(0)(0) eosinophilic change:olfactory epithelium 13 0 0 0 4 0 0 0 9 2 0 0 18 2 0 0 (72) (0) (0) (0) (57) (0) (0) (0) (75) (17) (0) (0) (82) (9) (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*100Significant difference; $*:P \le 0.05$ **: $P \le 0.01$ Test of Chi Square

(HPT150)

: RAT F344/DuCri

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

REPORT TYPE : A1 SEX : MALE

ANIMAL.

PAGE: 2 Group Name Control 1000 ppm 2000 ppm 4000 ppm No. of Animals on Study 18 22 12 Grade Findings (%) (%) [Respiratory system] nasal cavit <18> < 7> <12> eosinophilic change:respiratory epithelium 0 0 0 0 0 0 0 0 (6)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (9)(0)(0)(0) inflammation: foreign body 6 1 0 0 0 0 5 0 0 (33) (6) (0) (0) (57) (0) (0) (0) (25) (0) (0) (0) (23) (0) (0) (0) inflammation:respiratory epithelium 0 0 0 0 0 0 0 0 3 0 0 0 (0)(0)(0)(0) (0)(0)(0)(0) (25) (0) (0) (0) (0)(0)(0)(0) respiratory metaplasia:olfactory epithelium 4 0 0 0 0 0 0 0 3 0 3 1 (22) (0) (0) (0) (0)(0)(0)(0) (25) (0) (0) (0) (14) (5) (0) (0) respiratory metaplasia:gland 0 0 0 15 0 (89) (0) (0) (0) (71) (0) (0) (0) (75) (0) (0) (0) (68) (0) (0) (0) atrophy:olfactory epithelium 6 0 0 0 0 0 3 0 0 0 (33) (0) (0) (0) (0)(0)(0)(0) (0)(0)(0)(0) (14) (0) (0) (0) erosion:olfactory epithelium 0 0 0 0 0 0 0 0 0 0 0 (0)(0)(0)(0) (14) (0) (0) (0) (0)(0)(0)(0) (0)(0)(0)(0) thickening of bone:turbinate 0 0 0 0 3 (6)(0)(0)(0) (0)(0)(0)(0) (8) (0) (0) (0) (14) (0) (0) (0)

4 : Severe

Grade 1 : Slight 2 : Moderate 3 : Marked < 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

(HPT150)

b

ANIMAL : RAT F344/DuCrj

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

PAGE: 3

Organ	Group Nam No. of An Grade Findings	Control imals on Study 18 1 2 3 4 (%) (%) (%) (%)	1000 ppm 7 1 2 3 4 (%) (%) (%) (%)	2000 ppm 12 1 2 3 4 (%) (%) (%) (%)	4000 ppm 22 1 2 3 4 (%) (%) (%) (%)
[Respiratory:	system]				
nasopharynx	eosinophilic change	<18> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<pre></pre>	<12> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<22> 1 0 0 0 (5) (0) (0) (0)
larynx	mineralization	0 0 0 0 (0) (0) (0) (0)	< 7> 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 0 0 0	<22> 1 0 0 0 (5) (0) (0) (0)
lung	congestion	<18> 0 1 0 0 (0) (6) (0) (0)	<pre></pre>	\(\lambda 12 \rangle \) \(1 0 0 0 \) \((8) (0) (0) (0) (0) \)	<22>> 1 0 0 0 (5) (0) (0) (0)
	interstitial penumonia	6 2 0 0 (33) (11) (0) (0)	1 2 0 0 (14) (29) (0) (0)	5 2 2 0 (42) (17) (17) (0)	8 1 0 0 (36) (5) (0) (0)
	mineralization:artery	0 1 0 0 (0) (6) (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (8) (0) (0) (0)	0 0 0 0 0 (0) (0)
[Hematopoieti	c system]				
oone marrow	increased hematopoiesis	5 0 0 0 (28) (0) (0) (0)	4 0 0 0 (57) (0) (0) (0)	2 0 0 0 (17) (0) (0) (0)	222> 11 0 0 0 (50) (0) (0) (0)
(a) (c)	1: Slight 2: Moderate 3: Marked a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 lifference; $*: P \le 0.05$ **: $P \le 0.01$	4 : Severe			

(HPT150)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1
SEX : MALE

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

PAGE: 4

Organ	Findings	Group Name Control No. of Animals on Study 18 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 7 1 2 3 4 (%) (%) (%) (%)	2000 ppm 12 1 2 3 4 (%) (%) (%) (%)	4000 ppm 2Z 1 2 3 4 (%) (%) (%) (%)
[Nematopoieti	c system]				
bone marrow	erythropoiesis:increased	1 0 0 0 (6) (0) (0) (0)	<pre></pre>	1 0 0 0 (8) (0) (0) (0)	\(\lambda 22 \rangle \) 1
lymph nade	Lymphadenitis	1 0 0 0 (6) (0) (0) (0)	<pre></pre>	<12> 0 0 0 0 0 0 0 0 0 0 0 0	<22> 0 0 0 0 (0) (0) (0) (0)
	follicular hyperplasia	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (5) (0) (0) (0)
spleen	congestion	(18) 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	<12> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	2 0 0 0 (9) (0) (0) (0)
	karyorrhexis	0 0 0 0 0 (0) (0)	1 0 0 0 (14) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	deposit of hemosiderin	4 2 0 0 (22) (11) (0) (0)	0 1 0 0 (0) (14) (0) (0)	0 2 0 0 (0) (17) (0) (0)	2 3 2 0 (9) (14) (9) (0)
	fibrosis	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 (5) (9) (0) (0)

(HPT150)

(c)

b: Number of animals with lesion

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

c:b/a*100

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCri

REPORT TYPE : A1 SEX : MALE DEAD AND MORIBUND ANIMALS (0-105W)

SEX PAGE: 5 Group Name Control 1000 ppm 2000 ppm 4000 ppm No. of Animals on Study 18 7 12 22 3 4 Findings (%) (%) (%) [Hematopoietic system] spleen <18> < 7> (12) extramedullary hematopoiesis 2 1 0 1 1 1 0 3 1 0 0 2 5 0 (0)(11)(6)(0) (14) (14) (14) (0) (25) (8) (0) (0) (5)(9)(23)(0) [Circulatory system] heart <18> < 7> <12> thrombus 0 0 0 0 0 1 0 0 0 0 1 0 1 0 (0)(0)(0)(0) (0)(0)(14)(0) (0)(0)(0)(0) (5)(0)(5)(0) mineralization 0 (6)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(5)(0)(0) myocardial fibrosis 1 2 0 0 0 2 1 (6)(11)(0)(0) (43) (0) (0) (0) (25) (0) (0) (0) (9)(5)(0)(0) artery/aort <18> < 7> <12> (22) mineralization 0 0 1 0 0 0 0 0 0 0 0 0 0 0 1 0 (0)(0)(6)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(5)(0) periarteritis nodosa 0 0 0 1 0 0 (0)(0)(0)(0) (0)(0)(0)(14) (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 * 100Significant difference; $*: P \le 0.05$ $**: P \le 0.01$ Test of Chi Square

(HPT150)

STUDY NO. : 0278 ANIMAL : RAT F344/DuCrj HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

REPORT TYPE : A1

SEX : MALE

DEAD AND MORIBUND ANIMALS (0-105W)

0rgan	Findings	Group Name Control No. of Animals on Study 18 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 7 1 2 3 4 (%) (%) (%) (%)	2000 ppm 12 1 2 3 4 (%) (%) (%) (%)	4000 ppm 22 1 2 3 4 (%) (%) (%) (%)
[Digestive	system]				
tooth	dysplasia	2 4 0 0 (11) (22) (0) (0)	3 0 0 0 (43) (0) (0) (0)	(12) 1 2 0 0 (8) (17) (0) (0)	<pre></pre>
congue	mineralization	0 0 1 0 (0) (0) (6) (0)	< 7> 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 0 0 0	<22> 0 0 1 0 (0) (0) (5) (0)
	arteritis	0 0 0 0 0 (0) (0)	1 0 0 0 (14) (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0
tomach	mineralization	<18> 0 0 1 0 (0) (0) (6) (0)	< 7> 0 0 0 0 (0) (0) (0) (0)	<12> 0 0 0 0 0 0 0 0 0 0 0 0	<pre></pre>
	inflammatory infiltration	1 0 0 0 0 (6) (6) (7)	0 0 0 0 0	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	periarteritis nodosa	0 0 0 0 0 (0) (0)	0 0 1 0 (0) (14) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	ulcer:forestomach	0 1 3 0 (0) (6) (17) (0)	0 0 1 0 (0) (14) (0)	0 1 0 2 (0) (8) (0) (17)	0 3 1 0 (0) (14) (5) (0)
rade a > b c) ignificant	1: Slight 2: Moderate a: Number of animals examined at 1 b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **:				

(HPT150)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Group Name Control No. of Animals on Study 18 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 7 1 2 3 4 (%) (%) (%) (%)	2000 ppm 12 1 2 3 4 (%) (%) (%) (%)	4000 ppm 22 1 2 3 4 (%) (%) (%) (%)
Digestive sy	vstem]				
tomach	hyperplasia:forestomach	18> 1 0 3 0 (6) (0) (17) (0)	7> 0 0 1 0 (0) (0) (14) (0)	(12) 1 1 1 0 (8) (8) (8) (0)	222> 1 0 0 0 (5) (0) (0) (0)
	erosion:glandular stomach	2 0 0 0 (11) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 1 0 0 (5) (5) (0) (0)
	ulcer:glandular stomach	0 2 0 0 (0) (11) (0) (0)	0 0 0 0 0	0 0 0 0 0 0 (0) (0)	0 1 0 0 (0) (5) (0) (0)
nall intes	periarteritis nodosa	0 0 0 0 (0) (0) (0) (0)	0 0 1 0 (0) (0) (14) (0)	0 0 0 0 (0) (0) (0) (0)	<22> 0 0 0 0 0 0 0 0 0 0 0 0
ver	herniation	18> 1 0 0 0 (6) (0) (0) (0)	< 7> 0 0 0 0 0 0 0 0 0 0 0 0	<12> 1 0 0 0 (8) (0) (0) (0)	<22> 1 0 0 0 (5) (0) (0) (0)
	necrosis:central	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	3 0 0 0 (14)(0)(0)(0)
	necrosis:focal	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (8) (0) (0) (0)	0 2 0 0 (0) (9) (0) (0)
c)	1: Slight 2: Moderate a: Number of animals examined at t b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **:				

ANIMAL : RAT F344/DuCrj

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

PAGE: 8

Organ	Findings	Group Name Control No. of Animals on Study 18 Grade 1 2 3 (%) (%) (%) (1000 ppm 7 7 (%) (%) (%) (%)	2000 ppm 12 1 2 3 4 (%) (%) (%) (%)	4000 ppm 22 1 2 3 4 (%) (%) (%) (%)
Digestive	system]				
iver	fatty change	(18) 0 0 2 (0)(0)(11)(<pre></pre>	(12) 0 0 0 0 (0) (0) (0) (0)	<22> 1 0 0 0 (5) (0) (0) (0)
	fatty change:central	0 0 0 0 (0) (0 1 0 0	1 0 2 0 (8) (0) (17) (0)	0 1 1 0 (0) (5) (5) (0)
	fatty change:peripheral	1 1 1 (6) (6) (6) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	2 0 0 0 0 (17) (0) (0) (0)	1 0 0 0 (5) (0) (0) (0)
	perivascular inflammation	0 1 0 (0) (6) (0) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	acidophilic cell focus	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 0 0 0 (0) (0)	1 0 0 0 (5) (0) (0) (0)
	basophilic cell focus	0 0 0 0 (0) (0 2 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	1 0 0 0 0 (8) (0) (0) (0)	2 2 0 0 (9) (9) (0) (0)
	vacuplated cell focus	0 0 0 0 (0) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	1 0 0 0 0 (8) (0) (0) (0)	1 0 0 0 (5)(0)(0)(0)
	spongiosis hepatis	2 0 0 (11) (0) (0) (0 0 0 0 0	0 0 0 0 0 (0) (0)	1 0 0 0 (5) (0) (0) (0)

<a>>

a: Number of animals examined at the site

b

b: Number of animals with lesion

(c)

c:b/a*100

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

STUDY NO. : 0278 ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : MALE

PAGE: 9

0rgan	Group i No. of Grade Findings	Name Control Animals on Study 18 1 2 3 4 (%) (%) (%) (%)	1000 ppm 7 1 2 3 4 (%) (%) (%) (%)	2000 ppm 12 1 2 3 4 (%) (%) (%) (%)	4000 ppm 22 1 2 3 4 (%) (%) (%) (%)
[Digestive s	system]				
Liver	bile duct hyperplasia	\(\lambda 18 > \) \(13 3 1 0 \) \(\lambda 72 \right) \(\lambda 17 \right) \(\lambda 6 \right) \(\lambda 0 \right) \)	3 0 0 0 * (43) (0) (0) (0)	7 3 0 0 (58) (25) (0) (0)	\(\langle 22 \rangle \) 15
	bile ductular proliferation	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (5) (0) (0)
	biliary cyst	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 (0) (0)	1 0 0 0 0 (8) (0) (0) (0)	0 0 0 0 0 (0) (0)
pancreas	atrophy	3 1 0 0 (17) (6) (0) (0)	<pre></pre>	1 0 0 0 (8) (0) (0) (0)	222> 1 0 0 0 (5) (0) (0) (0)
[Urinary sys	stem]				
kidney	thrombus	<18> 0 0 0 0 (0) (0) (0) (0)	7> 1 0 0 0 (14) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
	cyst	0 1 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
Grade <a>> b (c) Significant	1: Slight 2: Moderate 3: Marka a: Number of animals examined at the site b: Number of animals with lesion c: b/a * 100 difference; *: $P \le 0.05$ **: $P \le 0.01$				-

(HPT150)

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : MALE

DEAD AND MORIBUND ANIMALS (0-105W)

Group Name Control 1000 ppm 2000 ppm 4000 ppm No. of Animals on Study 18 7 22 12 Findings_ (%) (%) (%) Organ_ [Urinary system] kidney <18> < 7> <12> hyaline droplet 0 1 0 0 0 0 0 (0)(0)(6)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) basophilic change 0 (6) (44) (0) (0) (0)(0)(0)(0) (17) (17) (0) (0) (32) (5) (0) (0) deposit of hemosiderin 0 5 0 0 3 2 0 0 1 (11) (0) (0) (0) (43) (0) (0) (0) (42) (8) (0) (0) (14) (9) (0) (0) chronic nephropathy 2 4 2 8 3 5 1 3 5 7 (11) (22) (11) (44) (57) (43) (0) (0) (25) (42) (8) (25) (23) (32) (14) (18) mineralization:papilla 0 0 0 0 (6)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) mineralization:cortex 0 0 0 2 (11) (0) (0) (0) (0)(0)(0)(0) (0)(0)(0)(0) (9)(0)(0)(0) urothelial hyperplasia:pelivis 0 0 0 0 0 0 0 0 1 0 0 0 (0)(0)(0)(0) (0)(0)(0)(0) (8)(0)(0)(0) (9)(0)(0)(0) urin bladd <18> < 7> <12> hemorrhagic 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)(5) Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe

Test of Chi Square

(HPT150)

(a)

b (c) a: Number of animals examined at the siteb: Number of animals with lesion

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

c:b/a*100

BAIS3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE DEAD AND MORIBUND ANIMALS (0-105W)

PAGE: 11

Organ		Up Name Control of Animals on Study 18 de 1 2 3 4 (%) (%) (%) (%)	1000 ppm 7 1 2 3 4 (%) (%) (%) (%)	2000 ppm 12 1 2 3 4 (%) (%) (%) (%)	4000 ppm 22 1 2 3 4 (%) (%) (%) (%)
[Endocrine s	system]				
pituitary	cyst	<18> 0 0 0 0 0 0 0 0 0 0 0 0 0	<pre></pre>	1 0 0 0 (8) (0) (0) (0)	222> 2 0 0 0 (9) (0) (0) (0)
	hyperplasia	3 0 0 0 (17) (0) (0) (0)	1 1 0 0 (14) (14) (0) (0)	0 0 0 0 0 (0) (0)	6 3 0 0 (27) (14) (0) (0)
	Rathke pouch	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (8) (0) (0) (0)	0 0 0 0 0 (0) (0)
thyroid	C-cell hyperplasia	2 0 0 0 (11) (0) (0) (0)	<pre></pre>	1 0 0 0 (8) (0) (0) (0)	<22>> 1 0 0 0 (5) (0) (0) (0)
	focal follicular cell hyperplasia	0 1 0 0 (0) (0)	1 0 0 0 0 (20) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (5) (0) (0)
adrena l	peliosis-like lesion	<18> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	3 0 0 0 (25) (0) (0) (0)	(22) 1 0 0 0 (5) (0) (0) (0)
	hyperplasia:cortical cell	1 0 0 0 (6) (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (5)(0)(0)(0)
Grade (a) b (c)	1: Slight 2: Moderate 3: Ma: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; *: $P \le 0.05$ **: $P \le 0$				

(HPT150)

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : MALE

DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findings	Group Name Control No. of Animals on Study 18 Grade 1 2 3 4 (%) (%) (%) (%) (%)	$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	2000 ppm 12 1 2 3 4 (%) (%) (%) (%)	4000 ppm 22 1 2 3 4 (%) (%) (%) (%)
[Endocrine	system]				
adrena l	hyperplasia:medulla	<18> 2 2 0 0 (11) (11) (0) (0)	<pre></pre>	3 1 0 0 (25) (8) (0) (0)	<22> 2 4 0 0 (9) (18) (0) (0)
	focal fatty change:cortex	3 0 0 0 (17) (0) (0) (0)	0 0 0 0 0 (0) (0)	1 1 0 0 (8) (8) (0) (0)	1 2 0 0 (5) (9) (0) (0)
	focal hypertrophy:cortex	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	1 0 0 0 (14) (0) (0) (0)	0 1 0 0 0 (0) (0)	1 0 0 0 0 (5) (0) (0) (0)
[Reproducti	ive system]				
estis	atrophy	<17> 0 1 5 11 (0) (6) (29) (65)	<pre></pre>	(12> 0 2 1 8 (0) (17) (8) (67)	(22) 0 2 1 17 (0) (9) (5) (77)
	mineralization	1 0 0 0 (6) (0) (0) (0)	1 0 0 0 (14) (0) (0) (0)	2 0 0 0 (17) (0) (0) (0)	0 0 0 0 0
	arteritis	0 0 0 0 0 0 (0) (0)	1 0 0 0 (14) (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0
	interstitial cell hyperplasia	3 0 0 0 (18) (0) (0) (0)	2 0 0 0 (29) (0) (0) (0)	3 0 0 0 (25) (0) (0) (0)	1 0 0 0 0 0 (5) (0) (0)
Grade <a> b	1: Slight 2: Moderate a: Number of animals examined at th b: Number of animals with lesion c: b/a * 100	3 : Marked 4 : Severe e site			

(HPT150)

BAIS3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX

: MALE

DEAD AND MORIBUND ANIMALS (0-105W)

Group Name Control 1000 ppm 2000 ppm 4000 ppm No. of Animals on Study 18 7 12 22 Findings [Reproductive system] epididymis ⟨18⟩ < 7> <12> spermatogenic granuloma 0 0 0 0 0 1 0 0 0 0 0 0 0 0 0 0 (0)(0)(0)(0) (0)(14)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) prostate <18> < 7> <12> inflammation 1 1 0 0 0 0 0 0 1 0 0 0 1 0 0 0 (6)(6)(0)(0) (0)(0)(0)(0) (8) (0) (0) (0) (5)(0)(0)(0) mammary gl <18> < 7> <12> duct ectasia 3 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 (17) (0) (0) (0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) galactocele 0 0 0 0 0 0 0 0 (11) (0) (0) (0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) prep/cli gl <18> < 7> <12> duct ectasia 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 (6)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) [Nervous system] spinal cord <18> 1 0 0 0 0 0 0 0 0 < 7> 0 0 0 0 gliosis 0 0 0 0 (0)(0)(0)(0) (14) (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 b (c) c:b/a*100Significant difference; $*:P \le 0.05$ **: $P \le 0.01$ Test of Chi Square

(HPT150)

BAIS3

ANIMAL : RAT F344/DuCrj

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

PAGE: 14

Organ	Findings	Group Name Control No. of Animals on Study 18 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 7 1 2 3 4 (%) (%) (%) (%)	2000 ppm 12 1 2 3 4 (%) (%) (%) (%)	4000 ppm 22 1 2 3 4 (%) (%) (%) (%)
[Special sen	se organs/appandage]				
өуө	cataract	<18> 0 0 0 0 0 0 0 0 0 0 0	<pre></pre>	1 0 0 0 (8) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
	retinal atrophy	1 0 0 0 (6) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 1 (0) (0) (8)	0 0 0 1 (0) (0) (5)
	keratitis	1 0 0 0 (6) (6) (7)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	3 0 0 0 (14) (0) (0) (0)
	iritis	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	2 0 0 0 0 (9) (0) (0) (0)
	degeneration:cornea	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (8) (0) (0) (0)	0 0 0 0 0 0 (0) (0)
	mineralization:cornea	8 0 0 0 (44)(0)(0)(0)	3 0 0 0 (43) (0) (0) (0)	4 0 0 0 0 (33) (0) (0) (0)	4 0 0 0 0 (18) (0) (0) (0)
Harder gl	atrophy	0 1 0 0 (0) (6) (0) (0)	<pre></pre>	\(\lambda 12 \rangle \) \(1 0 0 0 \) \(8) \(0) \(0) \(0) (0) \)	<22> 0 0 0 0 0 0 0 0 0 0 0
	degeneration	6 0 0 0 (33) (0) (0) (0)	1 1 0 0 (14) (14) (0) (0)	5 2 0 0 (42)(17)(0)(0)	8 0 0 0 (36) (0) (0) (0)

b

(a)

a: Number of animals examined at the site

b: Number of animals with lesion

(c) c:b/a*100

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

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1
SEX : MALE

PAGE: 15

Organ	Group No. or Grade Findings	Name Control Animals on Study 18 1 2 3 4 (%) (%) (%) (%)	1000 ppm 7 1 2 3 4 (%) (%) (%) (%)	2000 ppm 12 1 2 3 4 (%) (%) (%) (%)	4000 ppm 22 1 2 3 4 (%) (%) (%) (%)
[Special sens	se organs/appandage]				
nasolacr d	inflammation	0 0 0 0 (0) (0) (0) (0)	7> 1 0 0 0 (14) (0) (0) (0)	2 0 0 0 (17) (0) (0) (0)	<22> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
Musculoskele	etal systemj				
nuscle	mineralization	0 0 0 0 (0) (0) (0) (0)	<pre></pre>	\(\lambda 12 \rangle \) \[1 1 0 0 \\ (8) (8) (0) (0) \]	\(\frac{\lambda22\rangle}{1} \\ 1 \\ 1 \\ 0 \\ 0 \\ (5) \\ (5) \\ (0) \\ (\qu
	inflammation	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (5) (0) (0) (0)
	arteritis	0 0 0 0 0 0 (0) (0)	1 0 0 0 (14) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
ane	asteasclerosis	0 0 0 0 (0) (0) (0) (0)	<pre></pre>	<12> 1 0 0 0 (8) (0) (0) (0)	<22> 0 0 0 0 0 0 0 0 0 0 0 0
Grade (a > b (c) Significant o	1: Slight 2: Moderate 3: Mark a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; $*: P \le 0.05$ **: $P \le 0.01$				

APPENDIX J3

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY, RAT: MALE: SACRIFICED ANIMALS (2-YEAR STUDY)

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

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE

PAGE: 1

Organ	1	Group Name Control No. of Animals on Study 32 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 43 1 2 3 4 (%) (%) (%) (%)	2000 ppm 38 1 2 3 4 (%) (%) (%) (%)	4000 ppm 28 1 2 3 4 (%) (%) (%) (%)
[Integumentar	ry system/appandage]				
skin/app	hyperplasi a: epidermis	<32> 0 0 0 0 (0) (0) (0) (0)	<43> 0 0 0 0 (0) (0) (0) (0)	<38> 0 1 0 0 (0) (3) (0) (0)	<28> 0 0 0 0 0 0 0 0 0 0 0
	scab	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (4) (0) (0)
	epidermal cyst	0 0 0 0 0 (0) (0)	0 2 0 0 (0) (5) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
subcutis	abscess	<32> 0 0 0 0 0 0 0 0 0 0 0	<43> 1 0 0 0 (2) (0) (0) (0)	<38> 0 0 0 0 (0) (0) (0) (0)	<28> 0 0 0 0 0 (0) (0) (0) (0)
[Respiratory	system]				
nasal cavit	thrombus	<32> 0 0 0 0 (0) (0) (0) (0)	<43> 0 0 0 0 (0) (0) (0) (0)	<38> 2 0 0 0 (5) (0) (0) (0)	<28> 0 0 0 0 (0) (0) (0) (0)
	mineralization	21 0 0 0 (66) (0) (0) (0)	36 0 0 0 (84) (0) (0) (0)	30 0 0 0 (79) (0) (0) (0)	14 1 0 0 (50) (4) (0) (0)
Grade < a > b (c) Significant (1: Slight 2: Moderate 3 a: Number of animals examined at the sib: Number of animals with lesion c: b / a * 100 difference; $*: P \le 0.05$ **: $P \le 0.05$				

(HPT150)

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

: MALE

SACRIFICED ANIMALS (105W)

SEX PAGE: 2 Group Name Control 1000 ppm 2000 ppm 4000 ppm No. of Animals on Study 32 43 38 28 2 3 3 4 Organ Findings_ (%) (%) (%) (%) (%) (%) [Respiratory system] nasal cavit ⟨32⟩ <43> ⟨38⟩ <28> ecsinophilic change:olfactory epithelium 22 5 3 0 17 3 16 19 3 0 15 8 5 (69) (16) (9) (0) (53) (40) (7) (0) (50) (42) (8) (0) (54) (29) (18) (0) eosinophilic change:respiratory epithelium 0 3 0 10 (16) (0) (0) (0) (2)(0)(0)(0) (8) (0) (0) (0) (36) (0) (0) (0) inflammation:foreign body 1 0 0 9 3 0 0 9 0 0 0 10 (47) (3) (0) (0) (21) (7) (0) (0) (24) (0) (0) (0) (36) (0) (0) (0) inflammation:respiratory epithelium 0 0 (3)(0)(0)(0) (2)(0)(0)(0) (0)(3)(0)(0) (0)(0)(0)(0) inflammation:olfactory epithelium 0 (0)(0)(0)(0) (2)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) respiratory metaplasia:olfactory epithelium 11 6 0 11 14 0 () ** (34) (19) (3) (0) (26) (2) (0) (0) (37) (0) (0) (0) (14) (0) (0) (0) respiratory metaplasia:gland 30 0 0 0 0 0 25 (94) (0) (0) (0) (98) (0) (0) (0) (92) (0) (0) (0) (89) (0) (0) (0) atrophy:olfactory epithelium 0 0 * (16) (0) (0) (0) (2)(0)(0)(0) (0)(0)(0)(0) (4)(0)(0)(0)

Grade (a) 1 : Slight

2 : Moderate

3 : Marked

4 : Severe

a : Number of animals examined at the site

b

b: Number of animals with lesion

c:b/a * 100 (c)

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

(HPT150)

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : MALE

SACRIFICED ANIMALS (105W)

Organ		p Name Control of Animals on Study 32 de <u>1 2 3 4 (%) (%) (%) (%) (%) (%) (%) (%) (%) (%)</u>	1000 ppm 43 1 2 3 4 (%) (%) (%) (%)	2000 ppm 38 1 2 3 4 (%) (%) (%) (%)	4000 ppm 28 1 2 3 4 (%) (%) (%) (%)
[Respiratory	system]				
nasal cauit	thickening of bone:turbinate	\$32> 5 0 0 0 (16) (0) (0) (0)	3 0 0 0 (7) (0) (0) (0)	38> 1 0 0 0 (3) (0) (0) (0)	28> 1 0 0 0 (4) (0) (0) (0)
nasopharynx	inflammation	32> 3 0 0 0 (9) (0) (0) (0)	<43> 0 0 0 0 (0) (0) (0) (0)	<38> 0 0 0 0 0 0 0 0 0 0 0	<28> 0 0 0 0 0 (0) (0) (0) (0)
larynx	inflammation	<32> 0 0 0 0 (0) (0) (0) (0)	<43> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<38> 0 0 0 0 0 0 0 0 0 0 0	<28> 1 0 0 0 (4) (0) (0) (0)
lung	foreign body granuloma	32> 0 1 0 0 (0) (3) (0) (0)	<43> 0 0 0 0 (0) (0) (0) (0)	<38> 0 0 0 0 0 0 0 0 0 0 0 0	<28> 0 0 0 0 0 0 0 0 0 0 0
	osseous metaplasia	1 0 0 0 0 (3) (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	1 0 0 0 (3) (0) (0) (0)	1 0 0 0 (4) (0) (0) (0)
	interstitial penumonia	17 4 0 0 (53) (13) (0) (0)	35 0 0 0 ** (81) (0) (0) (0)	27 5 1 0 (71) (13) (3) (0)	12 2 0 0 (43) (7) (0) (0)
	bronchiolar-alveolar cell hyperplasia	3 0 0 0 0	3 0 0 0 0 (7) (0) (0) (0)	1 0 0 0 0 (3) (0) (0) (0)	1 0 0 0 (4) (0) (0) (0)
Grade < a > b (c)	1: Slight 2: Moderate 3: Ma a: Number of animals examined at the site b: Number of animals with lesion c: b/a * 100	rked 4 : Severe			

(HPT150)

BAIS3

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

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : MALE

Organ	No	Dup Name Control of Animals on Study 32 ade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 43 1 2 3 4 (%) (%) (%) (%)	2000 ppm 38 1 2 3 4 (%) (%) (%) (%)	4000 ppm 28 1 2 3 4 (%) (%) (%) (%)
[Respiratory	system]				
lung	mineralization:artery	32> 0 0 0 0 (0) (0) (0) (0)	2 0 0 0 (5) (0) (0) (0)	<pre></pre>	(28) 1 0 0 0 (4) (0) (0) (0)
	endothelial cell hyperplasia	0 0 0 0 0 0 (0)	1 0 0 0 0 (2) (3) (4)	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
[Hematopoieti	c system]				
bone marrow	granulation	32> 1 0 0 0 (3) (0) (0) (0)	(43) 0 0 0 0 (0) (0) (0) (0)	38> 0 0 0 0 (0) (0) (0) (0)	<28> 0 0 0 0 0 0 0 0 0 0 0 0
	increased hematopoiesis	13 0 0 0 (41) (0) (0) (0)	16 0 0 0 (37) (0) (0) (0)	13 0 0 0 (34) (0) (0) (0)	16 0 0 0 (57) (0) (0) (0)
lymph nade	lymphadenitis	(32> 1 0 0 0 (3) (0) (0) (0)	<43> 1 0 0 0 (2) (0) (0) (0)	<38> 0 0 0 0 0 0 0 0 0 0 0	<28> 1 0 0 0 (4) (0) (0) (0)
	follicular hyperplasia	1 0 0 0 0 0 (3) (3) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
Grade <a>> b (c) Significant c	1: Slight 2: Moderate 3: a : Number of animals examined at the site b : Number of animals with lesion c: b / a * 100 lifference; $*: P \le 0.05$ **: $P \le 0$		-		

(HPT150)

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX

: MALE

SACRIFICED ANIMALS (105W)

Organ	_ Findings	Group Name Control No. of Animals on Study 32 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 43 1 2 3 4 (%) (%) (%) (%)	2000 ppm 38 1 2 3 4 (%) (%) (%) (%)	4000 ppm 28 1 2 3 4 (%) (%) (%) (%)
Hematopoi	etic system]				
spleen	ectopic tissue	<32> 0 0 1 0 (0) (0) (3) (0)	<pre></pre>	<38> 0 0 0 0 0 (0) (0) (0) (0)	<pre></pre>
	congestion	13 4 0 0 (41) (13) (0) (0)	3 1 0 0 ** (7) (2) (0) (0)	2 0 0 0 *** (5) (0) (0) (0)	9 1 0 0 (32) (4) (0) (0)
	deposit of hemosiderin	2 0 0 0 0 (6) (6) (70) (70)	7 0 0 0 0 (16) (0) (0) (0)	9 0 0 0 0 (24) (0) (0) (0)	6 0 0 0 (21) (0) (0)
	fibrosis	1 0 0 0 (3) (0) (0) (0)	1 1 0 0 (2) (2) (0) (0)	3 2 0 0 (8) (5) (0) (0)	5 3 0 0 * (18) (11) (0) (0)
	extramedullary hematopoiesis	2 0 0 0 (6) (6) (7) (7)	1 0 0 0 0 (2) (0) (0) (0)	3 1 0 0 (8) (3) (0) (0)	3 0 1 0 (11) (0) (4) (0)
	splenitis	0 1 0 0 (0) (3) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (4) (0) (0) (0)
	stromal hyperplasia	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 (0) (0)	0 1 0 0 (0) (4) (0) (0)
(Circulato	ry system]				
neart	necrosis:focal	32> 1 0 0 0 (3) (0) (0) (0)	<43> 0 0 0 0 (0) (0) (0) (0)	38> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>
Grade <a>> b (c)	1: Slight 2: Moderate a: Number of animals examined at t b: Number of animals with lesion c: b/a * 100 t difference; *: P ≤ 0.05 **:				

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1 SEX

: MALE

Organ	Findings	Group Name Control No. of Animals on Study 32 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 43 1 2 3 4 (%) (%) (%) (%)	2000 ppm 38 1 2 3 4 (%) (%) (%) (%)	4000 ppm 28 1 2 3 4 (%) (%) (%) (%)
(Circulatory	system]				
heart	myocardial fibrosis	32> 3 0 0 0 (9) (0) (0) (0)	<43> 13 0 0 0 (30) (0) (0) (0)	\(\langle 38 \rangle \) 17	<28> 5 0 0 0 (18) (0) (0) (0)
artery/aort	arteritis	<32> 0 0 0 0 0 0 0 0 0 0 0	<43> 0 0 0 0 (0) (0) (0) (0)	38> 0 0 0 0 (0) (0) (0) (0)	<28> 0 2 0 0 0 0) (7) (0) (0)
[Digestive sy	stem]				
tooth	dysplasia	32> 7 1 0 1 (22) (3) (0) (3)	(43) 11 2 0 0 (26) (5) (0) (0)	38> 6 4 0 0 (16) (11) (0) (0)	(28) 11 2 0 0 (39) (7) (0) (0)
tongue	mineralization	<32> 0 0 0 0 (0) (0) (0) (0)	<43> 0 0 0 0 (0) (0) (0) (0)	<38> 1 0 0 0 (3) (0) (0) (0)	<28> 2 0 0 0 (7) (0) (0) (0)
	abscess	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)
	arteritis	2 0 0 0 0 (6) (6) (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (3) (0) (0) (0)	2 0 0 0 0 (7) (0) (0) (0)
(a) b (c)	1: Slight 2: Moderate 3 a: Number of animals examined at the s b: Number of animals with lesion c: b / a * 100 ifference; $*: P \le 0.05$ **: $P \le 0.05$				

(HPT150)

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX

: MALE

SACRIFICED ANIMALS (105W)

PAGE: 7 Group Name Control 1000 ppm 2000 ppm 4000 ppm No. of Animals on Study 32 43 38 28 Grade Findings_ [Digestive system] esophagus ⟨32⟩ <43> ⟨38⟩ C-cell hyperplasia 0 0 0 0 0 0 0 0 (0)(0)(0)(0) (0)(0)(0)(0) (3)(0)(0)(0) (0)(0)(0)(0) focal follicular cell hyperplasia 0 (0)(0)(0)(0) (0)(0)(0)(0) (3)(0)(0)(0) (0)(0)(0)(0) stomach <32> <43> ⟨38⟩ <28> inflammatory infiltration 0 0 0 0 0 0 0 (3)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) ulcer:forestomach 1 0 0 0 0 0 (0)(3)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) hyperplasia:forestomach (0)(0)(3)(0) (2)(0)(0)(0) (0)(3)(0)(0) (7)(0)(0)(0) erosion:glandular stomach (3)(0)(0)(0) (2)(0)(0)(0) (0)(0)(0)(0) (4)(0)(0)(0) large intes <32> <43> (38) mineralization 0 0 0 0 0 0 0 0 0 0 0 0 (3)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) Grade 1: Slight 2 : Moderate 3 : Marked 4 : Severe <a>> a: Number of animals examined at the site b b: Number of animals with lesion (c) c:b/a * 100

(HPT150)

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

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : MALE SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name Control No. of Animals on Study 32 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 43 1 2 3 4 (%) (%) (%) (%)	2000 ppm 38 1 2 3 4 (%) (%) (%) (%)	4000 ppm 28 1 2 3 4 (%) (%) (%) (%)
[Digestive sy	stem]				
large intes	inflammation	<32> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	38> 1 0 0 0 (3) (0) (0) (0)	<28> 0 1 0 0 (0) (4) (0) (0)
liver	herniation	<32> 0 0 0 0 (0) (0) (0) (0)	43> 1 0 0 0 (2) (0) (0) (0)	<38> 1 0 0 0 (3) (0) (0) (0)	<28> 2 0 0 0 (7) (0) (0) (0)
	peliosis-like lesion	2 0 0 0 (6) (6) (7) (7)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	necrosis:focal	1 0 0 0 (3) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)
	fatty change	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	10 0 0 0 ** (26) (0) (0) (0)	4 0 0 0 0 (14) (0) (0) (0)
	fatty change:peripheral	1 0 0 0 0 (3) (0) (0) (0)	4 9 0 0 ***	4 0 0 0 0 (11) (0) (0)	1 0 0 0 0 (4) (0) (0) (0)
	granulation	6 0 0 0 (19) (0) (0) (0)	5 0 0 0 (12) (0) (0) (0)	8 0 0 0 (21) (0) (0) (0)	3 0 0 0 0 (11) (0) (0) (0)
	clear cell focus	2 0 0 0 (6) (6) (7) (7)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	1 1 0 0 (4) (4) (0) (0)

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

b: Number of animals with lesion b

(c) c:b/a * 100

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

(HPT150)

BAIS3

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE

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

PAGE: 9

Organ	Findings	Group Name Control No. of Animals on Study 32 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 43 1 2 3 4 (%) (%) (%) (%)	2000 ppm 38 1 2 3 4 (%) (%) (%) (%)	4000 ppm 28 1 2 3 4 (%) (%) (%) (%)
Digestive s	system]				
iver	acidophilic cell focus	\(\lambda 32 \rangle \) 17	23 5 2 0 (53) (12) (5) (0)	<38> 17 16 0 0 * (45) (42) (0) (0)	\(\lambda 28 \rangle \) 12
	basophilic cell focus	12 1 0 0 (38) (3) (0) (0)	29 5 0 0 ** (67) (12) (0) (0)	19 1 0 0 (50) (3) (0) (0)	9 4 1 0 (32) (14) (4) (0)
	vacuolated cell focus	9 0 0 0 0 (28) (0) (0) (0)	1 0 0 0 ** (2) (0) (0) (0)	11 1 0 0 (29) (3) (0) (0)	7 0 0 0 (25) (0) (0) (0)
	spongiosis hepatis	4 0 0 0 (13) (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	3 0 0 0 0 (8) (0) (0) (0)	5 0 0 0 (18) (0) (0) (0)
	bile duct hyperplasia	11 21 0 0 (34) (66) (0) (0)	32 4 0 0 ** (74) (9) (0) (0)	23 9 0 0 ** (61) (24) (0) (0)	12 14 1 0 (43) (50) (4) (0)
	bile ductular proliferation	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (4) (0) (0) (0)
	biliary cyst	2 0 0 0 (6) (6) (7) (7)	1 0 0 0 (2) (0) (0) (0)	1 0 0 0 0 (3) (0) (0)	0 0 0 0 0 (0) (0)
ancreas	atrophy	(32) 4 0 0 0 (13) (0) (0) (0)	<43> 2 1 0 0 (5) (2) (0) (0)	<38> 8 1 0 0 (21) (3) (0) (0)	<28> 8 0 0 0 (29) (0) (0) (0)

(a)

a: Number of animals examined at the site

b

b: Number of animals with lesion

c:b/a*100 (c)

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

(HPT150)

SEX : MALE

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

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

PAGE: 10

Organ	Findings	Group Name Control No. of Animals on Study 32 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 43 1 2 3 4 (%) (%) (%) (%)	2000 ppm 38 1 2 3 4 (%) (%) (%) (%)	4000 ppm 28 1 2 3 4 (%) (%) (%) (%)
[Digestive s	ystem]				
pancreas	inflammatory infiltration	32> 1 0 0 0 (3) (0) (0) (0)	<43> 0 0 0 0 (0) (0) (0) (0)	<38> 0 0 0 0 0 0 0 0 0 0 0	<28> 0 0 0 0 0 0 0 0 0 0
	islet cell hyperplasia	2 0 0 0 0 (6) (6) (7)	1 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	hyperplasia:acinar cell	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (3) (0) (0) (0)	0 0 0 0 0 (0) (0)
[Urinary sys	tem]				
cidney	basophilic change	32> 15 17 0 0 (47) (53) (0) (0)	<pre></pre>	\(\lambda 38 \rangle \) 22 8 0 0 ** (58) (21) (0) (0)	<pre></pre>
	deposit of hemosiderin	13 0 0 0 (41) (0) (0) (0)	26 0 0 0 (60) (0) (0) (0)	27 0 0 0 * (71) (0) (0) (0)	19 2 0 0 * (68) (7) (0) (0)
	easinophilic body	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (0)
	chronic nephropathy	0 0 14 18 (0) (0) (44) (56)	0 7 28 7 ** (0) (16) (65) (16)	2 7 21 8 ** (5) (18) (55) (21)	1 5 14 7 * (4) (18) (50) (25)

(HPT150)

: RAT F344/DuCrj

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

REPORT TYPE : A1 : MALE

ANIMAL

SACRIFICED ANIMALS (105W)

Group Name Control 1000 ppm 2000 ppm 4000 ppm No. of Animals on Study 32 43 38 28 Findings [Urinary system] kidney <32> <43> ⟨38⟩ hydronephrosis 0 0 0 0 0 0 0 1 0 0 0 0 0 0 (0)(0)(0)(0) (0)(0)(0)(0) (0)(3)(0)(0) (0)(0)(0)(0) urothelial hyperplasia:pelivis 0 0 0 0 0 0 0 0 1 0 0 0 0 0 0 0 (0)(0)(0)(0) (0)(0)(0)(0) (3)(0)(0)(0) (0)(0)(0)(0) urin bladd <32> <43> <38> (27) hemorrhagic 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) [Endocrine system] pituitary <43> ⟨38⟩ <28> angiectasis 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) cyst 0 3 (0)(0)(0)(0) (7)(2)(0)(0) (11) (0) (0) (0) (11) (0) (0) (0) hyperplasia 19 5 2 0 11 7 0 0 11 4 0 0 (31) (6) (0) (0) (44) (12) (5) (0) (29) (18) (0) (0) (39) (14) (0) (0) Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe (a) a: Number of animals examined at the site b b: Number of animals with lesion (c) c:b/a * 100 Significant difference; * : $P \le 0.05$ ** : $P \le 0.01$ Test of Chi Square

(HPT150)

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

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE

PAGE: 12

Organ		O Name Control of Animals on Study 32	1000 ppm 43 1 2 3 4 (%) (%) (%) (%)	2000 ppm 38 1 2 3 4 (%) (%) (%) (%)	4000 ppm 28 1 2 3 4 (%) (%) (%) (%)
(Endocrine s	ystem]				
pituitary	Rathke pouch	<32> 0 0 0 0 (0) (0) (0) (0)	3 0 0 0 (7) (0) (0) (0)	<38> 1 0 0 0 (3) (0) (0) (0)	<28> 0 0 0 0 0 0 0 0 0 0 0 0 0 0
thyroid	ultimibranchial body remanet	<32> 0 0 0 0 (0) (0) (0) (0)	<43> 0 0 0 0 (0) (0) (0) (0)	<37> 0 0 0 0 0 0 0 0 0 0 0 0	<28> 1 0 0 0 (4) (0) (0) (0)
	adenomatous goiter	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	C-cell hyperplasia	7 0 0 0 (22) (0) (0) (0)	7 0 0 0 (16) (0) (0) (0)	5 2 0 0 (14) (5) (0) (0)	2 0 0 0 0 (7) (0) (0) (0)
	focal follicular cell hyperplasia	2 0 0 0 0 (6) (6) (70) (70)	3 0 0 0 0 (7) (0) (0) (0)	2 0 0 0 0 (5) (0) (0) (0)	1 0 0 0 0 (4) (0) (0) (0)
adrenal	peliosis-like lesion	<32> 4 0 0 0 (13) (0) (0) (0)	5 0 0 0 (12) (0) (0) (0)	<38> 7 0 0 0 (18) (0) (0) (0)	<28> 8 0 0 0 (29) (0) (0) (0)
	necrosis: focal	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)
Grade (a) b (c)	1: Slight 2: Moderate 3: Ma a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤ 0.0				

(HPT150)

SEX

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 : MALE SACRIFICED ANIMALS (105W)

PAGE: 13 Group Name Control 1000 ppm 2000 ppm 4000 ppm No. of Animals on Study 32 43 38 28 2 Grade 3 Findings_ (%) (%) (%) (%) (%) [Endocrine system] adrenal <32> <43> <38> <28> hyperplasia:cortical cell 0 0 1 0 0 6 1 0 0 5 0 0 (3)(0)(0)(0) (12) (2) (0) (0) (16) (3) (0) (0) (18) (0) (0) (0) hyperplasia:medulla 16 0 0 17 0 0 2 0 0 * 14 (19) (9) (0) (0) (37) (7) (0) (0) (45) (5) (0) (0) (50) (7) (0) (0) focal fatty change:cortex 6 1 0 0 7 2 0 0 7 4 0 0 5 2 0 0 (19) (3) (0) (0) (16) (5) (0) (0) (18) (11) (0) (0) (18) (7) (0) (0) focal hypertrophy:cortex 0 2 0 0 3 0 3 0 (6)(0)(0)(0) (5)(0)(0)(0) (8)(0)(0)(0) (11) (4) (0) (0) [Reproductive system] testis ⟨32⟩ atrophy 0 4 28 0 1 42 0 2 36 0 2 25 0 (0)(0)(13)(88) (0)(0)(2)(98) (0)(0)(5)(95) (0)(0)(7)(89) mineralization 1 0 0 0 0 0 0 0 0 0 (3)(0)(0)(0) (12) (0) (0) (0) (8)(0)(0)(0) (4)(0)(0)(0) arteritis (3)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe (a) a: Number of animals examined at the site b b: Number of animals with lesion (c) c:b/a*100

(HPT150)

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

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj

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

Organ		po Name Control of Animals on Study 32 de 1 2 3 4 (%) (%) (%) (%)	1000 ppm 43 1 2 3 4 (%) (%) (%) (%)	2000 ppm 38 1 2 3 4 (%) (%) (%) (%)	4000 ppm 28 1 2 3 4 (%) (%) (%) (%)
[Reproductive	system]				
testis	interstitial cell hyperplasia	<pre></pre>	\(\lambda 43 \rangle \) \(1 0 0 0 \) \(2 \rangle (0) (0) (0)	38> 1 0 0 0 (3) (0) (0) (0)	28> 1 0 0 0 (4) (0) (0) (0)
prostate	inflammation	<32> 4 0 0 0 (13) (0) (0) (0)	<43> 2 0 0 0 (5) (0) (0) (0)	38> 3 0 0 0 (8) (0) (0) (0)	28> 2 0 0 0 (7) (0) (0) (0)
mammary gl	duct ectasia	<32> 0 1 0 0 (0) (3) (0) (0)	<43> 2 0 0 0 (5) (0) (0) (0)	<38> 2 0 0 0 (5) (0) (0) (0)	<28> 0 0 0 0 0 0 0 0 0 0 0 0 0 0
	galactocele	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0)	0 1 0 0 (0) (0)
[Nervous syst	cem]				
brain	gliosis	<32> 0 0 0 0 (0) (0) (0) (0)	(43) 1 0 0 0 (2) (0) (0) (0)	<38> 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 (0) (0) (0) (0)
[Special sens	se organs/appandage]				
өуө	cataract	32> 1 0 0 0 (3) (0) (0) (0)	<43> 0 0 0 0 (0) (0) (0) (0)	3 0 0 0 (8) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
Grade <a>> b (c) Significant c	1: Slight 2: Moderate 3: Market a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; $*: P \le 0.05$ **: $P \le 0.05$				

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

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE

PAGE: 15

Organ	Findings	Group Name Control No. of Animals on Study 32 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 43 1 2 3 4 (%) (%) (%) (%)	2000 ppm 38 1 2 3 4 (%) (%) (%) (%)	4000 ppm 28 1 2 3 4 (%) (%) (%) (%)
[Special sens	e organs/appandage]				
еуе	retinal atrophy	<pre></pre>	<43> 0 0 0 0 (0) (0) (0) (0)	38> 1 1 2 1 (3) (3) (5) (3)	<pre></pre>
	phthisis bulbi	1 0 0 0 0 (3) (3) (0) (0)	1 0 0 0 0 (2) (0) (0)	2 0 0 0 0 (5) (0) (0)	0 0 0 0 0 (0) (0)
	degeneration:cornea	2 0 0 0 (6) (6) (7)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (4) (0) (0) (0)
	mineralization:cornea	25 0 0 0 (78) (0) (0) (0)	22 0 0 0 * (51) (0) (0) (0)	22 0 0 0 (58) (0) (0) (0)	13 0 0 0 * (46) (0) (0) (0)
Harder gt	atrophy	32> 0 1 0 0 (0) (3) (0) (0)	<43> 0 0 0 0 (0) (0) (0) (0)	<38> 0 0 0 0 0 0 0 0 0 0 0	<28> 0 0 0 0 0 0 0 0 0
	degeneration	16 1 0 0 (50) (3) (0) (0)	25 0 0 0 (58) (0) (0) (0)	20 1 0 0 (53) (3) (0) (0)	8 0 0 0 (29) (0) (0) (0)
	inflammatory infiltration	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (4) (0) (0) (0)
nasolacr d	inflammation	<32> 0 0 0 0 0 0 0 0 0 0 0	<43> 0 0 0 0 (0) (0) (0) (0)	<38> 0 0 0 0 0 0 0 0 0 0 0	2 0 0 0 (7) (0) (0) (0)

(a)

a: Number of animals examined at the site

b

b: Number of animals with lesion

(c) c:b/a*100

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

(HPT150)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (105W)

Group Name Control 1000 ppm 2000 ppm 4000 ppm No. of Animals on Study 32 43 38 28 3 Findings_ (%) (%) (%) (%) (%) (%) (%) [Musculoskeletal system] bone ⟨32⟩ <43> <38> osteosclerosis 2 0 0 0 0 0 0 0 0 0 0 (0)(0)(0)(0) (5)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) Grade 1:Slight 2 : Moderate 3 : Marked 4 : Severe (a) a: Number of animals examined at the site b b: Number of animals with lesion (c) c:b/a*100 Significant difference; $*:P \le 0.05$ **: $P \le 0.01$ Test of Chi Square (HPT150)

BAIS3

APPENDIX J4

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY, RAT: FEMALE: ALL ANIMALS (2-YEAR STUDY)

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

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : FEMALE

Organ	Мо	Dup Name Control of Animals on Study 50 ade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
[Integumentar	y system/appandage]				
skin/app	sebaceous hyperplasia	(50) 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)
[Respiratory:	system]				
nasal cavit	thrombus	(50) 1 0 0 0 (2) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	(50) 4 0 0 0 (8) (0) (0) (0)
	mineralization	26 0 0 0 (52) (0) (0) (0)	23 0 0 0 (46) (0) (0) (0)	25 0 0 0 (50) (0) (0) (0)	34 1 0 0 (68) (2) (0) (0)
	eosinophilic change:olfactory epithelium	20 24 5 0 (40) (48) (10) (0)	7 23 19 0 ** (14) (46) (38) (0)	11 25 13 0 (22) (50) (26) (0)	12 19 16 1 * (24) (38) (32) (2)
	eosinophilic change:respiratory epitheli	11 0 0 0 0 (22) (0) (0) (0)	27 2 0 0 ** (54) (4) (0) (0)	25 10 0 0 ** (50) (20) (0) (0)	26 1 0 0 ** (52) (2) (0) (0)
	inflammation:foreign body	2 0 0 0 0 (4) (0) (0) (0)	3 1 0 0 (6) (2) (0) (0)	5 0 0 0 (10) (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)
	inflammation:respiratory epithelium	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	2 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 (0) (0)
Grade <a>> b (c)	1: Slight 2: Moderate 3: a : Number of animals examined at the site b : Number of animals with lesion c: b / a * 100 ifference : $*: P \le 0.05$ **: $P \le 0$	Marked 4: Severe			

ANIMAL : RAT F344/DuC-j

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

REPORT TYPE : A1 SEX

: FEMALE

PAGE: 22

Organ	Group Name No. of Anima Grade	Control Is on Study 50 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
[Respiratory	system]	•			
nasal ca∪it	respiratory metaplasia:olfactory epithelium	<50> 1 0 0 0 (2) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)
	respiratory metaplasia:gland	45 0 0 0 (90) (0) (0) (0)	45 0 0 0 (90) (0) (0) (0)	47 0 0 0 (94) (0) (0) (0)	37 0 0 0 (74) (0) (0) (0)
	thickening of bone:turbinate	7 2 0 0 (14) (4) (0) (0)	19 3 0 0 * (38) (6) (0) (0)	6 2 0 0 (12) (4) (0) (0)	12 0 0 0 0 (24) (0) (0) (0)
Larynx	inflammation	\(\frac{50}{0} \) \(\begin{array}{ccccc} 1 & 0 & 0 & 0 \\ (& 2) & (& 0) & (& 0) & (& 0) \end{array}	<50> 3 0 0 0 (6) (0) (0) (0)	3 0 0 0 (6) (0) (0) (0)	(50) 1 1 0 0 (2) (2) (0) (0)
lung	cangestion	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 5 0 0 0 (10) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	<50> 3 0 0 0 (6) (0) (0) (0)
	osseous metaplasia	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)
	accumulation of foamy cells	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)
Grade <a>> b <a> Compared to the compa	1: Slight 2: Moderate 3: Marked a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 lifference: *: P ≤ 0.05 **: P ≤ 0.01 Tes	4 : Severe t of Chi Square			

(HPT150)

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

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : FEMALE

Organ	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
[Respiratory:	system]				
lung	interstitial penumonia	(50) 7 0 0 0 (14) (0) (0) (0)	<pre></pre>	(50) 13 3 0 0 (26) (6) (0) (0)	<pre></pre>
	bronchiolar-alveolar cell hyperplasia	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	2 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
	mineralization:artery	3 0 0 0 0	2 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
[Hematopoieti	c system]				
bone marrow	granulation	<pre></pre>	<50> 1 0 0 0 (2) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)
	increased hematopoiesis	5 0 0 0 (10) (0) (0) (0)	6 0 0 0 (12) (0) (0) (0)	5 0 0 0 (10) (0) (0) (0)	10 0 0 0 0 (20) (0) (0) (0)
	myelofibrasis	1 0 0 0 0 (2) (0) (0)	(0) (0) (0) (0)	0 0 0 0 0 (0)	1 0 0 0 0 (2) (0) (0) (0)
	erythropoiesis:increased	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 (0) (0)	4 0 0 0 0 (8) (0) (0) (0)
Grade <a>> b (c) Significant d	1: Slight 2: Moderate 3 a: Number of animals examined at the s b: Number of animals with lesion c: b / a * 100 ifference; $*: P \le 0.05$ **: $P \le 0.05$				

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : FEMALE

ALL ANIMALS (0-105W)

Organ	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
UI 9di (riidiigs	(h) (h) (h)	(%) (%) (%)	(%) (%) (%)	(%) (%) (%) (%)
[Nematopoieti	ic system]				
lymph node	lymphadenitis	<50> 0 0 0 0 (0) (0) (0) (0)	3 0 0 0 (6) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)
spleen	consestion	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 2 0 0 0 (4) (0) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)	<pre></pre>
	deposit of hemosiderin	13 0 0 0 (26) (0) (0) (0)	15 1 0 0 (30) (2) (0) (0)	12 0 0 0 (24) (0) (0) (0)	14 1 0 0 (28) (2) (0) (0)
	granulation	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)
	fibrosis	0 0 0 0 0 (0) (0)	3 0 0 0 0 (6) (6) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	4 0 0 0 0 (8) (0) (0) (0)
	extramedullary hematopoiesis	0 1 0 0 (0) (0) (0)	5 1 0 0 (10) (2) (0) (0)	4 1 1 0 (8) (2) (2) (0)	2 3 2 0 (4) (6) (4) (0)
	stromal hyperplasia	1 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0 (0) (0)
	increased:Leydig cell	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	1 0 0 0 (2) (0) (0) (0)

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

b: Number of animals with lesion b

c:b/a*100 (c)

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

(HPT150)

BAIS3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

ALL ANIMALS (0-105W)

SEX : FEMALE

Organ		co Name Control of Animals on Study 50 e	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
[Circulatory s	system]			,	
heart	thrombus	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 1 (0) (0) (0) (2)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 1 1 0 (0) (2) (2) (0)
	inflammation	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 (0) (0)	0 0 1 0 (0) (2) (0)
	myocardial fibrosis	3 0 0 0 (6) (0) (0) (0)	5 0 0 0 (10) (0) (0) (0)	4 0 0 0 0 (8) (0) (0) (0)	2 0 0 0 0 (4) (0) (0)
[Digestive sys	stem]				
tooth	dysplasia	<50> 1 2 0 0 (2) (4) (0) (0)	(50) 1 2 0 0 (2) (4) (0) (0)	<50> 2 1 0 0 (4) (2) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)
tongue	arteritis	<50> 4 0 0 0 (8) (0) (0) (0)	<50> 2 0 0 0 (4) (0) (0) (0)	<50> 5 0 0 0 (10) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)
salivary gl	atrophy	<50> 1 0 0 0 (2) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
Grade <a>> b (c) Significant d	1: Slight 2: Moderate 3: Ma a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 ifference; $*: P \le 0.05$ **: $P \le 0.0$				

(HPT150)

BAIS3

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

: FEMALE

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

Group Name Control 1000 ppm 2000 ppm 4000 ppm No. of Animals on Study 50 50 50 50

2 3 2 (%) Findings_ (%) (%) (%) (%) (%) (%)

[Digestive system]

stomach	<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)
mineralization	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	1 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0) (0)

	concretion	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)
--	------------	-----------------------	---------------------	----------------------------	-------------------

inflammatory infiltration	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)

ulcer:forestomach	0 0 2 0 (0) (4) (0)	0 1 2 0 (0) (2) (4) (0)	0 0 0 0 0 (0) (0)	0 1 4 0 (0) (2) (8) (0)

hyperplasia:forestomach	3 0 2 0	0 2 1 0	0 0 0 0	8 4 1 0
	(6)(0)(4)(0)	(0)(4)(2)(0)	(0) (0) (0) (0)	(16) (8) (2) (0)

erosion:glandular stomach	0 0 0 0	1 0 0 0	0 1 0 0	2 1 0 0
	(0)(0)(0)(0)	(2)(0)(0)(0)	(0)(2)(0)(0)	(4)(2)(0)(0)

ulcer:glandular stomach	0 0 0 0	2 0 0 0	1 0 0 0	2 0 0 0
	(0)(0)(0)(0)	(4)(0)(0)(0)	(2)(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; $*:P \le 0.05$ $**:P \le 0.01$ Test of Chi Square

(HPT150)

BAIS3

PAGE: 26

STUDY NO. : 0278 REPORT TYPE : A1

SEX : FEMALE

ANIMAL : RAT F344/DuCrj

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

PAGE: 27

Organ	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 (%) (%) (%)	4 (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
[Digestive	system]					
liver	herniation	<50> 2 0 0 (4) (0) (0)		<50> 3 0 0 0 (6) (0) (0) (0)	<50> 2 0 0 0 (4) (0) (0) (0)	<50> 0 0 0 0 0 0 0 0 0 0 0
	peliosis-like lesion	1 0 0 (2) (0) (0)		0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)
	necrosis:central	0 0 0 0		0 0 0 0 0 (0) (0)	0 0 1 0 (0) (2) (0)	1 0 0 0 0 (2) (0) (0) (0)
	necrosis:focal	0 0 0 0		0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	1 0 0 0 (2) (0) (0) (0)
	fatty change	0 0 0 0		0 1 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	fatty change:central	0 0 1		0 0 1 0 (0) (2) (0)	1 0 0 0 0 (2) (0) (0) (0)	1 1 4 0 (2) (2) (8) (0)
	fatty change:peripheral	3 0 0 (6) (0) (0)	0 (0)	15 25 1 0 ** (30) (50) (2) (0)	8 29 1 0 ** (16) (58) (2) (0)	7 23 2 0 ** (14) (46) (4) (0)
	granulation	31 7 0 (62) (14) (0)	0 (0)	29 13 0 0 (58) (26) (0) (0)	27 12 1 0 (54) (24) (2) (0)	15 10 1 0 * (30) (20) (2) (0)

Grade

1 : Slight

2 : Moderate

3 : Marked

4 : Severe

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

b: Number of animals with lesion

c:b/a*100 (c)

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

ANIMAL : RAT F344/DuCrj

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

REPORT TYPE : A1

SEX : FEMALE

ALL ANIMALS (0-105W)

Organ	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
[Digestive sys	stem]				
liver	perivascular inflammation	(50) 0 1 0 0 (0)(2)(0)(0)	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)
	fibrosis:focal	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (2) (0) (0) (0)
	acidophilic cell focus	2 1 0 0 (4) (2) (0) (0)	8 0 0 0 (16) (0) (0) (0)	9 5 0 0 *	13 10 0 0 ** (26) (20) (0) (0)
	basophilic cell focus	18 0 0 0 (36) (0) (0) (0)	28 8 1 0 ** (56) (16) (2) (0)	15 25 0 0 ** (30) (50) (0) (0)	11 23 2 0 *** (22) (46) (4) (0)
	vacuolated cell focus	2 0 0 0 (4) (0) (0) (0)	7 0 0 0 (14) (0) (0) (0)	12 1 0 0 ** (24) (2) (0) (0)	8 3 0 0 * (16) (6) (0) (0)
	mixed cell facus	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	1 2 0 0 (2) (4) (0) (0)
	bile duct hyperplasia	1 0 1 0 (2) (0) (2) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)
	bile ductular proliferation	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	0 1 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)

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

(HPT150)

BAIS3

SEX : FEMALE

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

PAGE: 29

Organ	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
[Digestive s	ystem]				
pancreas	atrophy	3 1 0 0 (6) (2) (0) (0	<50> 2 0 0 0 (4) (0) (0) (0)	<50> 2 0 0 0 (4) (0) (0) (0)	<50> 3 0 0 0 (6) (0) (0) (0)
	hyperplasia:acinar cell	0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 0 (0)
Urinary sys	tem]				
idney	hyaline droplet	<50> 0 0 0 0 (0) (0) (0) (0	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
	basophilic change	18 3 0 0 (36) (6) (0) (0	3 0 0 0 *** (6) (0) (0) (0)	3 0 0 0 *** (6) (0) (0) (0)	5 0 0 0 ** (10) (0) (0) (0)
	deposit of hemosiderin	45 0 0 0 (90)(0)(0)(0	44 0 0 0 (88) (0) (0) (0)	43 2 0 0 (86) (4) (0) (0)	44 1 0 0 (88) (2) (0) (0)
	eosinophilic body	0 0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)
	inflammation	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 1 0 (0) (0) (0)

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

b : Number of animals with lesion b

(c) c:b/a*100

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

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : FEMALE

Organ		Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
(Urinary sys	stem]				
kidney	chronic nephropathy	<pre></pre>	<pre></pre>	<pre></pre>	<50> 27 6 5 0 ** (54) (12) (10) (0)
	hydronephrasis	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 1 0 (0) (2) (0)	0 0 0 0 0 (0) (0)
	mineralization:cortico-medullary junct	0 0 0 0 0 (0) (0) (0)	1 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)
	mineralization:papilla	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)
•	mineralization:pelvis	0 0 0 0 0 (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	2 0 0 0 0 (4) (0) (0) (0)
(Endocrine s	system]				
pituitary	angiectasis	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 6 1 0 0 * (12) (2) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
	hemorrhage	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)
Grade (a) b (c) Significant	1: Slight 2: Moderate 3 a: Number of animals examined at the si b: Number of animals with lesion c: b/a * 100 difference; $*: P \le 0.05$ **: $P \le 0.05$				

(HPT150)

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

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 SEX : FEMALE

Organ		Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
(Endocrine s	system]				
pituitary	cyst	(50) 17 2 0 0 (34) (4) (0) (0)	(50) 13 4 0 0 (26) (8) (0) (0)	(50) 13 3 1 0 (26) (6) (2) (0)	(50) 10 3 0 0 (20) (6) (0) (0)
	hyperplasia	14 3 I 0 (28) (6) (2) (0)	6 7 0 0 (12) (14) (0) (0)	13 2 0 0 (26) (4) (0) (0)	7 1 1 0 (14) (2) (2) (0)
thyroid	ultimibranchial body remanet	49> 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)
	C-cell hyperplasia	7 0 0 0 (14) (0) (0) (0)	2 0 0 0 0 (4) (0) (0) (0)	3 1 0 0 (6) (2) (0) (0)	11 0 0 0 (22) (0) (0) (0)
	focal follicular cell hyperplasia	0 0 0 0 0 (0)	2 0 0 0 0 (4) (0) (0) (0)	3 0 0 0 (6) (0) (0) (0)	0 0 0 0 0 (0) (0)
adrenal	peliosis-like lesion	27 17 0 0 (54) (34) (0) (0)	<50> 31 12 0 0 (62) (24) (0) (0)	<50> 23 19 0 0 (46) (38) (0) (0)	<50> 26 15 1 0 (52) (30) (2) (0)
	extramedullary hematopoiesis	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (2) (0) (0) (0)	2 0 0 0 0 (4) (0) (0) (0)
Grade <a>a> b (c) Significant	1: Slight 2: Moderate 3 a: Number of animals examined at the si b: Number of animals with lesion c: b / a * 100 difference; *: $P \le 0.05$ **: $P \le 0.05$				

(HPT150)

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

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE

PAGE: 32

Organ	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
(Endocrine	system]				
adrena l	hyperplasia:cortical cell	3 0 0 0 (6) (0) (0) (0)	(50) 6 0 0 0 (12) (0) (0) (0)	(50) 5 1 0 0 (10) (2) (0) (0)	<50> 4 0 0 0 (8) (0) (0) (0)
	hyperplasia:medulla	3 1 0 0 (6) (2) (0) (0)	8 0 0 0 (16) (0) (0) (0)	4 1 0 0 (8) (2) (0) (0)	9 1 0 0 (18) (2) (0) (0)
	focal fatty change:cortex	10 3 0 0 (20) (6) (0) (0)	7 3 0 0 (14) (6) (0) (0)	5 3 0 0 (10) (6) (0) (0)	15 5 0 0 (30) (10) (0) (0)
	focal hypertrophy:cortex	1 0 0 0 (2) (0) (0) (0)	4 1 0 0 (8) (2) (0) (0)	4 1 0 0 (8) (2) (0) (0)	4 2 0 0 (8) (4) (0) (0)
[Reproducti	ue system]				
DUALY	cyst	<50> 0 0 1 0 (0) (0) (2) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 1 0 (0) (0) (2) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
uterus	cystic endometrial hyperplasia	<50> 13 0 0 0 (26) (0) (0) (0)	<50> 5 2 4 1 * (10) (4) (8) (2)	(50) 15 2 3 0 (30) (4) (6) (0)	<50> 5 0 4 0 * (10) (0) (8) (0)
Grade <a>> b (c) Significant	1: Slight 2: Moderate a: Number of animals examined at the b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P				

(HPT150)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 : FEMALE HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) ALL ANIMALS (0-105W)

PAGE: 33

Organ	Group Name No. of Anim Grade Findings	Control nals on Study 50 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
[Reproduction	ue system]				
mammary gl	duct ectasia	(50) 1 0 1 0 (2) (0) (2) (0)	2 0 0 0 (4) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	2 0 0 0 (4) (0) (0) (0)
	hyperplasia	2 0 0 0 0 (4) (0) (0)	1 0 0 0 0 (2) (0) (0)	0 0 0 0 0 (0) (0)	2 0 0 0 0 (4) (0) (0) (0)
	galactocele	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 (0) (0)	0 0 0 1 (0) (0) (2)	0 1 0 0 (0) (0)
[Nervous sy:	stem]				
orain	hemorrhage	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 1 0 (0) (0) (2) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
[Special se	nse organs/appandage]				
эуө	cataract	1 0 0 0 (2) (0) (0) (0)	2 0 0 0 (4) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
Grade (a > b (c) Significant	1: Slight 2: Moderate 3: Marked a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤ 0.01 To	4 : Severe est of Chi Square			
(HPT150)			<u> </u>		

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : FEMALE

ALL ANIMALS (0-105W)

0rgan	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
(Special sens	se organs/appandage]				
еуе	retinal atrophy	(4)(0)(0)(0)	<50> 1 1 0 3 (2) (2) (0) (6)	5 0 1 1 (10) (0) (2) (2)	(50) 2 0 2 0 (4) (0) (4) (0)
	keratitis	2 0 0 0 0 (4) (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)
	phthisis bulbi	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0
	degeneration:comea	1 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)
	mineralization:cornea	1 0 0 0 0 (2) (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	2 0 0 0 0 (4) (0) (0) (0)
larder gl	degeneration	\(\langle 50 \rangle \) 17	<50> 27 0 0 0 (54) (0) (0) (0)	<50> 31 0 0 0 ** (62) (0) (0) (0)	<50> 21 0 0 0 (42) (0) (0) (0)
	lymphocytic infiltration	0 0 0 0 0 (0) (0)	2 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)
nasolacr d	inflammation	\(\lambda 50 \rangle \) 11	<50> 3 0 0 0 * (6) (0) (0) (0)	<50> 2	(50) 7 0 0 0 (14) (0) (0) (0)

(a)

a: Number of animals examined at the site

b

b: Number of animals with lesion

c:b/a * 100 (c)

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

(HPT150)

BAIS3

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) ALL ANIMALS (0-105W)

PAGE: 35

	Grade	mals on Study 50 1 2 3 4	1000 ppm 50 1 2 3 4	2000 ppm 50 1 2 3 4	4000 ppm 50 1 2 3 4
)rgan	Findings	(%) (%) (%)	(%) (%) (%)	(%) (%) (%) (%)	(%) (%) (%)
Musculoske	pletal system]				
muscle	mineralization	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
ane	asteosclerasis	(50) 14 7 0 0 (28) (14) (0) (0)	<50> 16 7 3 0 (32) (14) (6) (0)	<50> 16 6 3 0 (32) (12) (6) (0)	<50> 13 6 0 0 (26) (12) (0) (0)
Grade (a > b (c) Significant	1: Slight 2: Moderate 3: Marked a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤ 0.01 T	4 : Severe est of Chi Square			

(HPT150)

APPENDIX J 5

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY, RAT: FEMALE: DEAD AND MORIBUND ANIMALS (2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 : FEMALE

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

PAGE: 16

Organ	1	Group Name Control No. of Animals on Study 5 Grade 1 2 3 4 (%) (%) (%) (%) (%)	1000 ppm 10 10 (%) (%) (%) (%)	2000 ppm 7 1 2 3 4 (%) (%) (%) (%)	4000 ppm 20 1 2 3 4 (%) (%) (%) (%)
Respiratory	system]				
masal cavit	thrombus ·	\(\ \ 5 \> \\ \ \ \ \ (\ 20) \ (\ 0) \ (\ 0) \ (\ 0) \ (\ 0) \ \)	(10) 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	<pre></pre>
	mineralization	3 0 0 0 0 (60) (60) (60) (70)	4 0 0 0 (40) (0) (0) (0)	5 0 0 0 (71) (0) (0) (0)	12 1 . 0 0 (60) (5) (0) (0)
	eosinophilic change:olfactory epithelic	2 3 0 0 (40)(60)(0)(0)	3 5 1 0 (30) (50) (10) (0)	3 2 1 0 (43) (29) (14) (0)	6 7 4 1 (30) (35) (20) (5)
	eosinophilic change:respiratory epithel	1 0 0 0 (20) (0) (0)	2 0 0 0 (20) (20) (0) (0)	1 1 0 0 (14) (14) (0) (0)	5 1 0 0 (25) (5) (0) (0)
	inflammation:respiratory epithelium	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (14) (0) (0) (0)	0 0 0 0 0 (0) (0)
	respiratory metaplasia:gland	4 0 0 0 (80) (0) (0) (0)	8 0 0 0 (80) (0) (0) (0)	6 0 0 0 0 (86) (0) (0) (0)	10 0 0 0 (50) (50) (60) (70)
	thickening of bone:turbinate	2 0 0 0 0 (40) (0) (0)	2 1 0 0 (20) (10) (0) (0)	1 0 0 0 0 (14) (0) (0) (0)	3 0 0 0 (15) (0) (0) (0)
ung	cangestion	< 5> 0 0 0 0 (0) (0) (0) (0)	4 0 0 0 (40) (0) (0) (0)	<pre></pre>	3 0 0 0 (15)(0)(0)(0)

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

b b: Number of animals with lesion

(c) c:b/a*100

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

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1
SEX : FEMALE

DEAD AND MORIBUND ANIMALS (0-105W)

0rgan	Group No. of Grade	ame Control Animals on Study 5 1 2 3 4 (%) (%) (%) (%)	1000 ppm 10 1 2 3 4 (%) (%) (%) (%)	2000 ppm 7 1 2 3 4 (%) (%) (%) (%)	4000 ppm 20 1 2 3 4 (%) (%) (%) (%)
[Respiratory	system]				
lung	interstitial penumonia	<pre></pre>	2 1 0 0 (20) (10) (0) (0)	<pre></pre>	\$\\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
(Nematopojeti	ic system]				
bone marrow	increased hematopoiesis	<pre></pre>	2 0 0 0 (20) (0) (0) (0)	7> 1 0 0 0 (14) (0) (0) (0)	<pre></pre>
	myelofibrosis	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0	1 0 0 0 (5) (0) (0) (0)
	erythropoiesis:increased	1 0 0 0 0 (20) (20) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	3 0 0 0 (15) (0) (0) (0)
lymph node	lymphadenitis	< 5> 0 0 0 0 (0) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	<pre></pre>	<20> 0 0 0 0 (0) (0) (0) (0)
spleen	congestion	< 5> 0 0 0 0 (0) (0) (0) (0)	<10> 2 0 0 0 (20) (0) (0) (0)	< 7> 0 0 0 0 0 (0) (0) (0) (0)	<pre></pre>
Grade <a>> b (c) Significant o	1: Slight 2: Moderate 3: Marka a: Number of animals examined at the site b: Number of animals with lesion c:b/a*100 difference; *:P≤0.05 **:P≤0.01				

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE DEAD AND MORIBUND ANIMALS (0-105W)

PAGE: 18 Group Name Control 1000 ppm 2000 ppm 4000 ppm No. of Animals on Study 5 10 20 3 3 Findings_ (%) (%) (%) [Hematopoietic system] spleen < 5> <10> < 7> ⟨20⟩ deposit of hemosiderin 0 0 0 1 0 0 0 0 0 (60) (0) (0) (0) (20) (10) (0) (0) (0)(0)(0)(0) (10) (5) (0) (0) fibrosis 0 0 0 (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (10) (0) (0) (0) extramedullary hematopoiesis 0 0 0 0 0 1 0 0 0 0 1 0 (0)(0)(0)(0) (0)(10)(0)(0) (0)(0)(14)(0) (0)(15)(10)(0) [Circulatory system] heart < 5> <10> < 7> thrombus 0 0 1 0 0 0 0 (0)(0)(0)(0) (0)(0)(0)(10) (0)(0)(0)(0) (0)(5)(5)(0) inflammation 0 0 0 0 0 1 0 0 (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(5)(0) myocardial fibrosis 0 0 0 0 0 0 0 0 1 0 0 0 2 0 (0)(0)(0)(0) (0)(0)(0)(0) (14) (0) (0) (0) (10) (0) (0) (0) [Digestive system] tooth < 5> <10> < 7> dysplasia 0 0 0 0 0 0 0 0 2 0 0 0 1 0 0 0 (0)(0)(0)(0) (0)(0)(0)(0) (29) (0) (0) (0) (5)(0)(0)(0)

(HPT150)

Grade

(a)

b

(c)

1 : Slight

c:b/a*100

2 : Moderate

a: Number of animals examined at the site

b: Number of animals with lesion

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

3 : Marked

4 : Severe

Test of Chi Square

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 SEX

: FEMALE

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

0rgan	Findings	Group Name Control No. of Animals on Study 5 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 10 1 2 3 4 (%) (%) (%) (%)	2000 ppm 7 1 2 3 4 (%) (%) (%) (%)	4000 ppm 20 1 2 3 4 (%) (%) (%) (%)
(Digestive sy	rstem]				
salivary gl	atrophy	0 0 0 0 (0) (0) (0) (0)	(10) 1 0 0 0 (10) (0) (0) (0)	< 7> 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 (0) (0) (0) (0)
stomach	hemorrhage	< 5> 0 0 0 0 (0) (0) (0) (0)	<10> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	<20> 0 0 0 0 0 0 0 0 0 0 0
	inflammatory infiltration	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)
	ulcer:forestomach	0 0 2 0 (0) (40) (0)	0 1 1 0 (0) (10) (10) (0)	0 0 0 0 0 (0) (0) (0)	0 1 4 0 (0) (5) (20) (0)
	hyperplasia:forestomach	0 0 2 0 (0) (40) (0)	0 2 1 0 (0) (20) (10) (0)	0 0 0 0 0 (0) (0)	5 4 1 0 (25) (20) (5) (0)
	erosion:glandular stomach	0 0 0 0 0 (0) (0)	1 0 0 0 0 (10) (10) (10)	0 1 0 0 (0) (14) (0) (0)	2 1 0 0 (10) (5) (0) (0)
	ulcer:9landular stomach	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (14) (0) (0) (0)	2 0 0 0 (10) (0) (0) (0)
liver	herniation	< 5> 0 0 0 0 (0) (0) (0) (0)	(10) 1 0 0 0 (10) (0) (0) (0)	<pre></pre>	<20> 0 0 0 0 0 0 0 0 0 0 0

(a)

a: Number of animals examined at the site b

b: Number of animals with lesion

c:b/a*100

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

(HPT150)

BAIS3

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

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1
SEX : FEMALE

PAGE: 20

Organ	I	Group Name Control No. of Animals on Study 5 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 10 1 2 3 4 (%) (%) (%) (%)	2000 ppm 7 1 2 3 4 (%) (%) (%) (%)	4000 ppm 20 1 2 3 4 (%) (%) (%) (%)
[Digestive	system]				
liver	necrosis:central	<pre></pre>	<10> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	<20> 1 0 0 0 (5) (0) (0) (0)
	necrosis:focal	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (5) (0) (0) (0)
	fatty change:central	0 0 1 0 (0) (20) (0)	0 0 1 0 (0) (10) (0)	0 0 0 0 0 (0) (0)	1 1 4 0 (5) (5) (20) (0)
	fatty change:peripheral	0 0 0 0 0 (0) (0)	1 2 0 0 (10) (20) (0) (0)	0 1 0 0 (0) (14) (0) (0)	3 3 1 0 (15) (15) (5) (0)
	granulation	2 0 0 0 (40) (0) (0) (0)	4 0 0 0 (40) (0) (0) (0)	1 0 0 0 (14) (0) (0) (0)	1 2 0 0 (5) (10) (0) (0)
	acidophilic cell focus	0 1 0 0 (0) (20) (0) (0)	0 0 0 0 0	0 0 0 0 0 0 (0) (0)	1 0 0 0 0 (5) (0) (0) (0)
	basophilic cell focus	0 0 0 0 0 0 (0)	2 0 0 0 0 (20) (0) (0)	1 0 0 0 (14) (0) (0) (0)	4 3 0 0 (20) (15) (0) (0)
	bile ductular proliferation	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)	0 1 0 0 (0) (5) (0) (0)
Grade (a) b (c)	1: Slight 2: Moderate 3 a: Number of animals examined at the si b: Number of animals with lesion c: b / a * 100 tdifference; *: P ≤ 0.05 **: P ≤				

(HPT150)

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1 SEX : FEMALE

Organ	No	coup Name Control . of Animals on Study 5 ade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 10 1 2 3 4 (%) (%) (%) (%)	2000 ppm 7 1 2 3 4 (%) (%) (%) (%)	4000 ppm 20 1 2 3 4 (%) (%) (%) (%)
[Digestive s	ystem]				
pancreas	atrophy	<pre></pre>	2 0 0 0 (20) (0) (0) (0)	<pre></pre>	20> 1 0 0 0 (5) (0) (0) (0)
Urinary sys	tem]				
<idney< td=""><td>hyaline droplet</td><td>< 5> 0 0 0 0 (0) (0) (0) (0)</td><td>0 0 0 0 (0) (0) (0) (0)</td><td>7> 1 0 0 0 (14) (0) (0) (0)</td><td>0 0 0 0 (0) (0) (0) (0)</td></idney<>	hyaline droplet	< 5> 0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	7> 1 0 0 0 (14) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
	deposit of hemosiderin	3 0 0 0 (60)(0)(0)(0)	7 0 0 0 (70) (0) (0) (0)	2 1 0 0 (29) (14) (0) (0)	14 1 0 0 (70) (5) (0) (0)
	inflammation	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 1 0 (0) (5) (0)
	chronic nephropathy	3 1 0 0 (60)(20)(0)(0)	3 2 0 0 (30) (20) (0) (0)	1 0 0 0 (14) (0) (0) (0)	9 0 0 0 0 (45) (0) (0) (0)
	mineralization:cortico-medullary junctic	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0	1 0 0 0 (5) (0) (0) (0)
	mineralization:papilla	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (5)(0)(0)(0)

(IIPT150)

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

BAIS3

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE

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

PAGE: 22

Organ	Findings	Group Name Control No. of Animals on Study 5 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 10 1 2 3 4 (%) (%) (%) (%)	2000 ppm 7 1 2 3 4 (%) (%) (%) (%)	4000 ppm 20 1 2 3 4 (%) (%) (%) (%)
[Endocrine s	ystem]				
pituitary	hemorrhage	< 5> 0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	<pre></pre>	<pre></pre>
	cyst	3 0 0 0 0 (60) (0) (0)	1 0 0 0 0 (10) (10) (10)	0 0 0 0 0 0 (0) (0)	1 1 0 0*
	hyperplasia	1 0 0 0 0 (20) (0) (0)	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	2 0 0 0 (10) (0) (0) (0)
thyroid	C-cell hyperplasia	<pre></pre>	0 0 0 0 (0) (0) (0) (0)	< 7> 0 0 0 0 (0) (0) (0) (0)	3 0 0 0 (15) (0) (0) (0)
adrena l	peliasis-like lesian	(5) 1 2 0 0 (20) (40) (0) (0)	<10> 4 3 0 0 (40) (30) (0) (0)	< 7> 1 3 0 0 (14) (43) (0) (0)	<20> 10 4 0 0 (50) (20) (0) (0)
	hyperplasia:cortical cell	0 0 0 0 0 (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	hyperplasia:medulla	0 0 0 0 0 (0) (0)	3 0 0 0 0 (30) (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	5 0 0 0 (25) (0) (0) (0)

(HPT150)

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

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE DEAD AND MORIBUND ANIMALS (0-105W)

Organ	Findines	Group Name Control No. of Animals on Study 5 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 10 1 2 3 4 (%) (%) (%) (%)	2000 ppm 7 1 2 3 4 (%) (%) (%) (%)	4000 ppm 20 1 2 3 4 (%) (%) (%) (%)
[Endocrine sy	rstem]				
adrenal	focal fatty change:cortex	\(\langle 5 \rangle \) \(1 0 0 0 \\ (20) (0) (0) (0) \)	(10) 1 1 0 0 (10) (10) (0) (0)	<pre></pre>	3 2 0 0 (15) (10) (0) (0)
	focal hypertrophy:cortex	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)	1 0 0 0 0 (14) (0) (0) (0)	1 2 0 0 (5) (10) (0) (0)
[Reproductive	e system]				
uterus	cystic endometrial hyperplasia	0 0 0 0 (0) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	<pre></pre>	200> 2 0 0 0 (10) (0) (0) (0)
mammary gl	duct ectasia	<pre></pre>	2 0 0 0 (20) (0) (0) (0)	< 7> 0 0 0 0 (0) (0) (0) (0)	<20> 1 0 0 0 (5) (0) (0) (0)
	hyperplasia	0 0 0 0 0 0 (0) (0)	1 0 0 0 0 0 10 10 10 10 10 10 10 10 10 1	0 0 0 0 0 0 (0) (0)	2 0 0 0 0 (10) (10) (10)
[Nervous syst	tem]				
brain	hemorrhage	0 0 0 0 (0) (0) (0) (0)	0 0 1 0 (0) (0) (10) (0)	<pre></pre>	<pre></pre>
Grade <a> > b <a> c) Significant of	1: Slight 2: Moderate a: Number of animals examined at the b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **:	3 : Marked 4 : Severe e site P ≦ 0.01 Test of Chi Square			

ANIMAL : RAT F344/DuCrj

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

0rgan		up Name Control of Animals on Study 5 de <u>1 2 3 4</u> (%) (%) (%) (%)	1000 ppm 10 1 2 3 4 (%) (%) (%) (%)	2000 ppm 7 1 2 3 4 (%) (%) (%) (%)	4000 ppm 20 1 2 3 4 (%) (%) (%) (%)
[Special sens	se organs/appandage]				
эуө	retinal atrophy	<pre></pre>	0 1 0 0 (0) (10) (0) (0)	7> 1 0 0 0 (14) (0) (0) (0)	<20> 0 0 0 0 0 0 0 0 0 0 0
	keratitis	0 0 0 0 0 0 (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (5) (0) (0) (0)
	phthisis bulbi	0 0 0 0 0 (0) (0)	1 0 0 0 (10) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	mineralization:cornea	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (5) (0) (0) (0)
arder gl	degeneration	<pre></pre>	7 0 0 0 (70) (0) (0) (0)	<pre></pre>	<20> 6 0 0 0 (30) (0) (0) (0)
	lymphocytic infiltration	0 0 0 0 0 0 (0) (0)	1 0 0 0 (10) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)
nasolacr d	inflammation	(5) 1 0 0 0 (20) (0) (0) (0)	<10> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	<20> 1 0 0 0 (5) (0) (0) (0)
Grade (a > b (c)	1: Slight 2: Moderate 3: Materials at the site b: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 sifference; $*: P \le 0.05$ **: $P \le 0.05$	arked 4: Severe			

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1
SEX : FEMALE

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

0rgan	No	Toup Name Control 5. of Animals on Study 5 ade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 10 · 1 2 3 4 (%) (%) (%) (%)	2000 ppm 7 1 2 3 4 (%) (%) (%) (%)	4000 ppm 20 1 2 3 4 (%) (%) (%) (%)
[Musculoskel	letal system]				
muscle	mineralization	< 5> 0 0 0 0 0 0 0 0 0 0 0	<10> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	<20> 0 0 0 0 (0) (0) (0), (0)
oone	osteosclerosis	<pre></pre>	4 0 1 0 (40) (0) (10) (0)	<pre></pre>	<20> 6 2 0 0 (30) (10) (0) (0)
Grade (a > b (c)	1: Slight 2: Moderate 3: a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤ 0				

BAIS3

APPENDIX J6

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY, RAT: FEMALE: SACRIFICED ANIMALS (2-YEAR STUDY)

SEX

ANIMAL : RAT F344/DuCrj

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

SACRIFICED ANIMALS (105W)

PAGE: 17

		roup Name Control o. of Animals on Study 45	1000 ppm 40	2000 ppm 43	4000 ppm 30
Organ		1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)
[Integumentar	y system/appandage]				
skin/app	sebaceous hyperplasia	<pre></pre>	(40) 0 0 0 0 (0) (0) (0) (0)	43> 1 0 0 0 (2) (0) (0) (0)	<30> 0 0 0 0 0 0 0 0 0 0 0
[Respiratory	system]				
nasal cavit	mineralization	<45> 23 0 0 0 (51) (0) (0) (0)	19 0 0 0 (48) (0) (0) (0)	20 0 0 0 (47) (0) (0) (0)	22 0 0 0 (73) (0) (0) (0)
	eosinophilic change:olfactory epithelium	18 21 5 0 (40) (47) (11) (0)	4 18 18 0 ** (10) (45) (45) (0)	8 23 12 0 (19) (53) (28) (0)	6 12 12 0 * (20) (40) (40) (0)
	eosinophilic change:respiratory epitheli	10 0 0 0 0 (22) (0) (0) (0)	25 2 0 0 ** (63) (5) (0) (0)	24 9 0 0 ** (56) (21) (0) (0)	21 0 0 0 ***
	inflammation:foreign body	2 0 0 0 0 (4) (0) (0) (0)	3 1 0 0 (8) (3) (0) (0)	5 0 0 0 (12) (0) (0) (0)	1 0 0 0 0 (3) (0) (0) (0)
	inflammation:respiratory epithelium	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)
	respiratory metaplasia:olfactory epithel	1 0 0 0 0 (2) (0) (0) (0)	1 0 0 0 (3) (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	1 0 0 0 0 (3) (0) (0)
Grade (a) b	1: Slight 2: Moderate 3: a: Number of animals examined at the site b: Number of animals with lesion c: b/a * 100	Marked 4: Severe			

(HPT150)

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1 SEX : FEMALE

PAGE: 18

Organ	Findings	No. of Animals on Study Grade 1 2 (%) (%)	45 2 3 4 %) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	4000 ppm 30 1 2 3 4 (%) (%) (%) (%)
(Respiratory sy	stem]					
nasal cauit	respiratory metaplasia:gland		<45> 0 0 0 0) (0) (0)	37 0 0 0 (93) (0) (0) (0)	41 0 0 0 (95) (0) (0) (0)	<pre></pre>
	thickening of bone:turbinate	5 2 (11) (4	2 0 0 4) (0) (0)	17 2 0 0 *** (43) (5) (0) (0)	5 2 0 0 (12) (5) (0) (0)	9 0 0 0 (30) (0) (0)
larynx	inflammation		<45> 0 0 0 0) (0) (0)	3 0 0 0 (8) (0) (0) (0)	3 0 0 0 (7) (0) (0) (0)	30> 1 1 0 0 (3) (3) (0) (0)
lung	congestion		<45> 0 0 0 0) (0) (0)	(40) 1 0 0 0 (3) (0) (0) (0)	<43> 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<30> 0 0 0 0 0 0 0 0 0
	osseous metaplasia		0 0 0	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (3) (0) (0) (0)
	accumulation of foamy cells		0 0 0	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	interstitial penumonia		0 0 0	19 0 0 0 ** (48) (0) (0) (0)	11 1 0 0 (26) (2) (0) (0)	11 0 0 0 (37) (0) (0) (0)

(HPT150)

b (c) b: Number of animals with lesion

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

c:b/a*100

SEX

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

: FEMALE

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

PAGE: 19

Organ	Findings	Group Name No. of Animals on Study Grade 1 (%)	Control 45 2 (%)	3 4 (%) (%)	1000 ppm 40 1 2 3 4 (%) (%) (%) (%)	2000 ppm 43 1 2 3 4 (%) (%) (%) (%)	4000 ppm 30 1 2 3 4 (%) (%) (%) (%)
[Respiratory:	system]						
lung	bronchiolar—alveolar cell hyperplasia	= -	<45> 0 (0) (0 0	\(\lambda 40 \rangle \) 1	<pre></pre>	<30> 0 0 0 0 0 0 0 0 0 0 0 0 0
	mineralization:artery	3 (7)	0 (0) (0 0 0 0) (0)	2 0 0 0 0 (5) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 (0) (0) (0)
[Hematopoieti	c system]						
bone marrow	sranulation	4 (9)	<45> 1 (2) (0 0 0 0) (0)	<pre></pre>	<43> 0 0 0 0 (0) (0) (0) (0)	(0) (0) (0) (0) (0) (0) (0) (0)
	increased hematopoiesis	5 (11)	0 (0) (0 0 0 0) (0)	4 0 0 0 0 (10) (10) (10) (10)	4 0 0 0 0 (9) (0) (0)	6 0 0 0 0 (20) (0) (0)
	myelofibrasis	1 (2)	0 (0) (0 0 0 0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	erythropoiesis:increased	0 (0)	0 (0) (0 0 0 0) (0)	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	1 0 0 0 0 (3) (0) (0) (0)
lymph nade	lymphadenitis	0 (0)	<45> 0 (0) (0 0 0 0) (0)	2 0 0 0 (5) (0) (0) (0)	<43> 0 0 0 0 (0) (0) (0) (0)	(30) (0)(0)(0)(0)(0)
<a>> b	1: Slight 2: Moderate a: Number of animals examined at the s b: Number of animals with lesion c: b / a * 100	3 : Marked 4 : Sever site	е				

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

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

: FEMALE

SACRIFICED ANIMALS (105W)

Organ	Findings	Group Name Control No. of Animals on Study 45 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 40 1 2 3 4 (%) (%) (%) (%)	2000 ppm 43 1 2 3 4 (%) (%) (%) (%)	4000 ppm 30 1 2 3 4 (%) (%) (%) (%)
[Hematopoie	tic system]				
spleen	congestion	<45> 0 0 0 0 (0) (0) (0) (0)	<40> 0 0 0 0 0 0 0 0 0 0 0 0 0 0	(43) 0 1 0 0 (0) (2) (0) (0)	<30> 0 0 0 0 (0) (0) (0) (0)
	deposit of hemosiderin	10 0 0 0 (22) (0) (0) (0)	13 0 0 0 (33) (0) (0) (0)	12 0 0 0 (28) (0) (0) (0)	12 0 0 0 (40) (0) (0) (0)
	granulation	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0)	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
	fibrosis	0 0 0 0 0 (0) (0)	3 0 0 0 0 (8) (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	2 0 0 0 0 (7) (0) (0) (0)
	extramedullary hematopoiesis	0 1 0 0 (0) (0) (0)	5 0 0 0 * (13) (0) (0) (0)	4 1 0 0 (9) (2) (0) (0)	2 0 0 0 0 (7) (0) (0) (0)
	stromal hyperplasia	1 0 0 0 0 (2) (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 0 0	0 0 0 0 0 0 (0) (0)
	increased:Leydig cell	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (3) (0) (0) (0)
[Circulator	y system]				
neart	myocardial fibrosis	3 0 0 0 (7) (0) (0) (0)	5 0 0 0 (13) (0) (0) (0)	3 0 0 0 (7) (0) (0) (0)	30> 0 0 0 0 (0) (0) (0) (0)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE

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

PAGE: 21

0rgan	Findings	Group Name Control No. of Animals on Study 45 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 40 1 2 3 4 (%) (%) (%) (%)	2000 ppm 43 1 2 3 4 (%) (%) (%) (%)	4000 ppm 30 1 2 3 4 (%) (%) (%) (%)
[Digestive sy	stem]				
tooth	dysplasia	<45> 1 2 0 0 (2) (4) (0) (0)	\(\langle 40 \rangle \) \(1 2 0 0 \\ (3) (5) (0) (0) \)	(43) 0 1 0 0 (0) (2) (0) (0)	(30) (0)(0)(0)(0)
tongue	arteritis	4 0 0 0 (9) (0) (0) (0)	2 0 0 0 (5) (0) (0) (0)	5 0 0 0 (12) (0) (0) (0)	30> 1 0 0 0 (3) (0) (0) (0)
salivary gl	atrophy	\(\lambda 45 \rangle \) \[1 0 0 0 (2) (0) \qquad (0) (\qquad 0) (0) \	<pre></pre>	<43> 0 0 0 0 (0) (0) (0) (0)	<30> 0 0 0 0 0 0 0 0 0 0 0
stomach	mineralization	<45> 0 0 0 0 (0) (0) (0) (0)	<40> 0 0 0 0 (0) (0) (0) (0)	<43> 1 0 0 0 (2) (0) (0) (0)	<30> 0 0 0 0 (0) (0) (0) (0)
	concretion	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0)
	ulcer:forestomach	0 0 0 0 0	0 0 1 0 (0) (3) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	hyperplasia:forestomach	3 0 0 0 (7) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	3 0 0 0 0 (10) (10) (10)

(a)

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

(c) c:b/a*100

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

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj

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

PAGE: 22

Organ	Findings	Group Name Control No. of Animals on Study 45 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 40 1 2 3 4 (%) (%) (%) (%)	2000 ppm 43 1 2 3 4 (%) (%) (%) (%)	4000 ppm 30 1 2 3 4 (%) (%) (%) (%)
[Digestive s	system]				
stomach	ulcer:glandular stomach	<45> 0 0 0 0 (0) (0) (0) (0)	2 0 0 0 (5) (0) (0) (0)	<43> 0 0 0 0 (0) (0) (0) (0)	30> 0 0 0 0 (0) (0) (0) (0)
liver	herniation	2 0 0 0 (4) (0) (0) (0)	<pre></pre>	<43> 2 0 0 0 (5) (0) (0) (0)	<30> 0 0 0 0 0 0 0 0 0 0 0
	peliasis-like lesian	1 0 0 0 0 (2) (3) (4) (5)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)
	necrosis:focal	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)
	fatty change	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (3) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	fatty change:central	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)
	fatty change:peripheral	3 0 0 0 (7) (0) (0) (0)	14 23 1 0 ** (35) (58) (3) (0)	8 28 1 0 ** (19) (65) (2) (0)	4 20 1 0 ** (13) (67) (3) (0)
	granulation	29 7 0 0 (64) (16) (0) (0)	25 13 0 0 * (63) (33) (0) (0)	26 12 1 0 (60) (28) (2) (0)	14 8 1 0 (47) (27) (3) (0)

(a)

a: Number of animals examined at the site

b

b: Number of animals with lesion

(c) c:b/a * 100

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

(HPT150)

SEX

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

: FEMALE

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

PAGE: 23

Organ	Findings	Group Name Control No. of Animals on Study 45 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 40 1 2 3 4 (%) (%) (%) (%)	2000 ppm 43 1 2 3 4 (%) (%) (%) (%)	4000 ppm 30 1 2 3 4 (%) (%) (%)
[Digestive	system]				
liver	perivascular inflammation	<45> 0 1 0 0 0 0 (2) (0) (0)	0 0 0 0 (0) (0) (0) (0)	(43> 1 0 0 0 (2) (0) (0) (0)	(30) (0)(0)(0)(0)
	fibrosis:focal	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (3) (0) (0)
	acidophilic cell focus	2 0 0 0 0 (4) (0) (0) (0)	8 0 0 0 (20) (0) (0) (0)	9 5 0 0 ** (21) (12) (0) (0)	12 10 0 0 ** (40) (33) (0) (0)
	basophilic cell focus	18 0 0 0 (40) (0) (0) (0)	26 8 1 0 ** (65) (20) (3) (0)	14 25 0 0 ** (33) (58) (0) (0)	7 20 2 0 ** (23) (67) (7) (0)
	vacuolated cell focus	2 0 0 0 (4) (0) (0) (0)	7 0 0 0 0 (18) (0) (0)	12 1 0 0 ** (28) (2) (0) (0)	8 3 0 0 ** (27) (10) (0) (0)
	mixed cell focus	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (3) (0) (0)	1 0 0 0 (2) (0) (0) (0)	1 2 0 0 (3) (7) (0) (0)
	bile duct hyperplasia	1 0 1 0 (2) (0) (2) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (3) (0) (0)
	bile ductular proliferation	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	0 1 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)

Grade < a > 1 : Slight

2 : Moderate

3 : Marked

4 : Severe

a : Number of animals examined at the site

b: Number of animals with lesion

(c) c:b/a*100

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

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (105W)

Organ	No	roup Name	1000 ppm 40 1 2 3 4 (%) (%) (%) (%)	2000 ppm 43 1 2 3 4 (%) (%) (%) (%)	4000 ppm 30 1 2 3 4 (%) (%) (%) (%)
[Digestive s	system]				
pancreas	atrophy	2 1 0 0 (4) (2) (0) (0)	<40> 0 0 0 0 0 0 0 0 0 0 0	<pre></pre>	<pre></pre>
	hyperplasia:acinar cell	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0)	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
[Urinary sys	stem]				
kidney	basophilic change	3 0 0 (40) (7) (0) (0)	3 0 0 0 ** (8) (0) (0) (0)	<43> 3 0 0 0 ** (7) (0) (0) (0)	5 0 0 0 * (17) (0) (0) (0)
	deposit of hemosiderin	42 0 0 0 (93) (0) (0) (0)	37 0 0 0 (93) (0) (0) (0)	41 1 0 0 (95) (2) (0) (0)	30 0 0 0 0 (100) (0) (0) (0)
-	eosinophilic body	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)
	chronic nephropathy	5 22 14 3 (11) (49) (31) (7)	19 19 2 0 ** (48) (48) (5) (0)	18 17 5 0 ** (42) (40) (12) (0)	18 6 5 0 ** (60) (20) (17) (0)
	hydronephrosis	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 1 0 (0) (2) (0)	0 0 0 0 0 (0) (0)
Grade (a) b (c)	1: Slight 2: Moderate 3: a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤ 0				

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

SEX

: FEMALE

SACRIFICED ANIMALS (105W)

Organ		Group Name Control No. of Animals on Study 45 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 40 1 2 3 4 (%) (%) (%) (%)	2000 ppm 43 1 2 3 4 (%) (%) (%) (%)	4000 ppm 30 1 2 3 4 (%) (%) (%) (%)
[Urinary sys	stem]				
kidney	mineralization:cortico-medullary junct	ion	(40) 1 0 0 0 (3) (0) (0) (0)	(43) 0 0 0 0 (0) (0) (0) (0)	30> 0 0 0 0 (0) (0) (0) (0)
	mineralization:pelvis	0 0 0 0 0 (0) (0)	0 0 0 0 0	0 0 0 0 0 0 (0) (0)	2 0 0 0 0 (7) (0) (0) (0)
[Endocrine s	system]				
pituitary	angiectasis	<45> 0 0 0 0 (0) (0) (0) (0)	(40> 0 0 0 0 (0) (0) (0) (0)	6 1 0 0 * (14) (2) (0) (0)	<30> 0 0 0 0 (0) (0) (0) (0)
	cyst	14 2 0 0 (31) (4) (0) (0)	12 4 0 0 (30) (10) (0) (0)	13 3 1 0 (30) (7) (2) (-0)	9 2 0 0 (30) (7) (0) (0)
	hyperplasia	13 3 1 0 (29) (7) (2) (0)	6 7 0 0 (15) (18) (0) (0)	13 2 0 0 (30) (5) (0) (0)	5 1 1 0 (17) (3) (3) (0)
thyroid	ultimibranchial body remanet	\(\begin{array}{cccccccccccccccccccccccccccccccccccc	<pre></pre>	<43> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>
Grade < a > b (c) Significant	1: Slight 2: Moderate 3 a: Number of animals examined at the si b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤				

(HPT150)

STUDY NO. : 0278 ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : FEMALE

PAGE: 26

Organ	Findings	Group Name Control No. of Animals on Study 45 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 40 1 2 3 4 (%) (%) (%) (%)	2000 ppm 43 1 2 3 4 (%) (%) (%) (%)	4000 ppm 30 1 2 3 4 (%) (%) (%) (%)
[Endocrine s	system]				
thyroid	C-cell hyperplasia	7 0 0 0 (16) (0) (0) (0)	2 0 0 0 (5) (0) (0) (0)	3 1 0 0 (7) (2) (0) (0)	30> 8 0 0 0 (27) (0) (0) (0)
	focal follicular cell hyperplasia	0 0 0 0 0 (0) (0)	2 0 0 0 0 (5) (0) (0) (0)	3 0 0 0 0 (7) (0) (0) (0)	0 0 0 0 0 (0) (0)
adrenal	peliosis-like lesion	26 15 0 0 (58) (33) (0) (0)	27 9 0 0 (68) (23) (0) (0)	22 16 0 0 (51) (37) (0) (0)	30> 16 11 1 0 (53) (37) (3) (0)
	extramedullary hematopoiesis	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	2 0 0 0 0 (7) (0) (0) (0)
	hyperplasia:cortical cell	3 0 0 0 (7) (0) (0) (0)	5 0 0 0 (13) (0) (0) (0)	5 1 0 0 (12) (2) (0) (0)	4 0 0 0 (13) (0) (0) (0)
	hyperplasia:medulla	3 1 0 0 (7) (2) (0) (0)	5 0 0 0 (13) (0) (0) (0)	4 1 0 0 (9) (2) (0) (0)	4 1 0 0 (13) (3) (0) (0)
	focal fatty change:cortex	9 3 0 0 (20) (7) (0) (0)	6 2 0 0 (15) (5) (0) (0)	5 3 0 0 (12) (7) (0) (0)	12 3 0 0 (40) (10) (0) (0)
	focal hypertrophy:cortex	1 0 0 0 (2) (0) (0) (0)	4 1 0 0 (10) (3) (0) (0)	3 1 0 0 (7) (2) (0) (0)	3 0 0 0 (10) (0) (0) (0)

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

b b: Number of animals with lesion

c : b / a * 100(c)

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

(HPT150)

BAIS3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

(HPT150)

SEX : FEMALE

SACRIFICED ANIMALS (105W)

0rgan	Findings	Group Name Control No. of Animals on Study 45 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 40 1 2 3 4 (%) (%) (%) (%)	2000 ppm 43 1 2 3 4 (%) (%) (%) (%)	4000 ppm 30 1 2 3 4 (%) (%) (%) (%)
[Reproductiv	ve system]				
DUARY	cyst	(45) 0 0 1 0 (0)(0)(2)(0)	0 0 0 0 (0) (0) (0) (0)	(43) 0 0 1 0 (0) (0) (2) (0)	<30> 0 0 0 0 0 0 0 0 0 0 0
uterus	cystic endometrial hyperplasia	(45) 13 0 0 0 (29) (0) (0) (0)	<40> 4 2 4 1 * (10) (5) (10) (3)	<pre></pre>	30> 3 0 4 0 * (10) (0) (13) (0)
mammary gl	duct ectasia	<45> 1 0 1 0 (2) (0) (2) (0)	<40> 0 0 0 0 (0) (0) (0) (0)	<43> 1 0 0 0 (2) (0) (0) (0)	30> 1 0 0 0 (3) (0) (0) (0)
	hyperplasia	2 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	galactocele	0 0 0 0 0 (0)	0 0 0 0 0 0 (0) (0)	0 0 0 1 (0) (0) (2)	0 1 0 0 (0) (0)
(Special sen	ise organs/appandage]				
еуе	cataract	<45> 1 0 0 0 (2) (0) (0) (0)	2 0 0 0 (5) (0) (0) (0)	(43) 1 0 0 0 (2) (0) (0) (0)	<pre></pre>
Grade <a>> b <a>c c c c c c c c c c c c c c c c c c c	1: Slight 2: Moderate a: Number of animals examined at th b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **:				

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : FEMALE

PAGE: 28

Organ	N	roup Name Control o. of Animals on Study 45 rade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 40 1 2 3 4 (%) (%) (%) (%)	2000 ppm 43 1 2 3 4 (%) (%) (%) (%)	4000 ppm 30 1 2 3 4 (%) (%) (%) (%)
[Special sens	se organs/appandage]				
өуе	retinal atrophy	<45> 2 0 0 0 (4) (0) (0) (0)	<pre></pre>	<pre></pre>	<30> 2
	keratitis	2 0 0 0 0 (4) (6) (6)	1 0 0 0 0 (3) (0) (0)	0 0 0 0 0 (0) (0) (. 0)	0 0 0 0 0 0 (0) (0)
	degeneration:cornea	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	mineralization:cornea	1 0 0 0 0 (2) (0) (0) (0)	1 0 0 0 0 (3) (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (3) (0) (0)
Harder gl	degeneration	45> 16 0 0 0 (36) (0) (0) (0)	<40> 20 0 0 0 (50) (0) (0) (0)	<43> 26 0 0 0 * (60) (0) (0) (0)	<30> 15 0 0 0 (50) (0) (0) (0)
	lymphocytic infiltration	0 0 0 0 0 0 (0) (0)	1 0 0 0 0 (3) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
nasolact d	inflammation	10 0 0 0 (22) (0) (0) (0)	3 0 0 0 (8) (0) (0) (0)	<pre></pre>	<30> 6 0 0 0 (20) (0) (0) (0)
Grade <a>> b (c) Significant d	1: Slight 2: Moderate 3: a: Number of animals examined at the sit b: Number of animals with lesion c: b / a * 100 lifference; $*: P \le 0.05$ **: $P \le 0.05$				

(HPT150)

BAIS3

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

PAGE: 29

BAIS3

SACRIFICED ANIMALS (105W)

SEX : FEMALE

Group Name Control 1000 ppm 2000 ppm 4000 ppm No. of Animals on Study 30 Grade Findings (%) [Musculoskeletal system] bone <45> <40> <43> osteosclerosis 13 6 0 0 12 7 2 0 15 6 2 0 7 4 0 0 (29) (13) (0) (0) (30) (18) (5) (0) (35) (14) (5) (0) (23) (13) (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*100Significant difference: $*: P \le 0.05$ **: $P \le 0.01$ Test of Chi Square (HPT150)

APPENDIX K 1

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS-TIME RELATED RAT: MALE $(\hbox{2-YEAR STUDY}\,)$

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

STUDY NO. : 0278

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

SEX : MALE

ime-related Weeks	Items	Group Name	Control	1000 ppm	2000 ppm	4000 ppm	
0 - 52	NO. OF EXAMINED ANIMALS		0	0	0	0	
	NO. OF ANIMALS WITH TUMORS		0	0	0	0	
	NO. OF ANIMALS WITH SINGLE TUMORS		0	0	Ů	0	
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	0	
	NO. OF BENIGN TUMORS		0	0	0	0	
	NO. OF MALIGNANT TUMORS		0	0	0	0	
	NO. OF TOTAL TUMORS		0	0	0	0	
53 - 78	NO. OF EXAMINED ANIMALS		2	1	1	4	
	NO. OF ANIMALS WITH TUMORS		2	1	1	4	
	NO. OF ANIMALS WITH SINGLE TUMORS		0	0	0	2	
	NO. OF ANIMALS WITH MULTIPLE TUMORS		2	1	1	2	
	NO. OF BENIGN TUMORS		2	1	1	2	
	NO. OF MALIGNANT TUMORS		3	1	1	4	
	NO. OF TOTAL TUMORS		5	2	2	6	
79 - 104	NO. OF EXAMINED ANIMALS		16	6	11	18	
	NO. OF ANIMALS WITH TUMORS		16	6	11	17	
	NO. OF ANIMALS WITH SINGLE TUMORS		1	1	1	1	
	NO. OF ANIMALS WITH MULTIPLE TUMORS		15	5	10	16	
	NO. OF BENIGN TUMORS		27	9	27	31	
	NO. OF MALIGNANT TUMORS		14	6	6	10	
	NO. OF TOTAL TUMORS		41	15	33	41	
105 - 105	NO. OF EXAMINED ANIMALS		32	43	38	28	
	NO. OF ANIMALS WITH TUMORS		32	43	38	20	
	NO. OF ANIMALS WITH SINGLE TUMORS		32 7	45 14	38 9	28 4	
	NO. OF ANIMALS WITH MULTIPLE TUMORS		25	29	29	24	
	NO. OF BENIGN TUMORS		68	87	80	71	
	NO. OF MALIGNANT TUMORS		6	8	12	13	
	NO. OF TOTAL TUMORS		74	95	92	84	

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

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

SEX : MALE

Time-relatedWeeks	Items	Group Name	Control	1000 ppm	2000 ppm	4000 ppm	
0 - 105	NO. OF EXAMINED ANIMALS		50	50	50	50	
	NO. OF ANIMALS WITH TUMORS NO. OF ANIMALS WITH SINGLE TUMORS NO. OF ANIMALS WITH MULTIPLE TUMORS		50 8 42	50 15 35	50 10 40	49 7 42	
	NO. OF BENIGN TUMORS NO. OF MALIGNANT TUMORS NO. OF TOTAL TUMORS		97 23 120	97 15 112	108 19 127	104 27 131	

(HPT070)

BAIS3

APPENDIX K 2

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS-TIME RELATED RAT: FEMALE $(\hbox{2-YEAR STUDY}\,)$

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

STUDY NO. : 0278 ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

SEX : FEMALE

Time-related Items Group Name 2000 ppm Control 1000 ppm 4000 ppm Weeks 0 - 52 NO. OF EXAMINED ANIMALS NO. OF ANIMALS WITH TUMORS NO. OF ANIMALS WITH SINGLE TUMORS NO. OF ANIMALS WITH MULTIPLE TUMORS NO. OF BENIGN TUMORS NO. OF MALIGNANT TUMORS NO. OF TOTAL TUMORS NO. OF EXAMINED ANIMALS 53 - 78 NO. OF ANIMALS WITH TUMORS NO. OF ANIMALS WITH SINGLE TUMORS NO. OF ANIMALS WITH MULTIPLE TUMORS NO. OF BENIGN TUMORS NO. OF MALIGNANT TUMORS NO. OF TOTAL TUMORS 79 - 104 NO. OF EXAMINED ANIMALS NO. OF ANIMALS WITH TUMORS NO. OF ANIMALS WITH SINGLE TUMORS NO. OF ANIMALS WITH MULTIPLE TUMORS NO. OF BENIGN TUMORS NO. OF MALIGNANT TUMORS NO. OF TOTAL TUMORS 105 - 105 NO. OF EXAMINED ANIMALS NO. OF ANIMALS WITH TUMORS NO. OF ANIMALS WITH SINGLE TUMORS NO. OF ANIMALS WITH MULTIPLE TUMORS NO. OF BENIGN TUMORS NO. OF MALIGNANT TUMORS NO. OF TOTAL TUMORS

(HPT070)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

SEX : FEMALE

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

PAGE: 4

Time-relatedWeeks	Items	Group Name	Control	1000 ppm	2000 ppm	4000 ppm	
0 - 105	NO. OF EXAMINED ANIMALS		50	50	50	50	
	NO. OF ANIMALS WITH TUMORS NO. OF ANIMALS WITH SINGLE TUMORS NO. OF ANIMALS WITH MULTIPLE TUMORS		41 23 18	43 21 22	40 13 27	45 23 22	
	NO. OF BENIGN TUMORS NO. OF MALIGNANT TUMORS NO. OF TOTAL TUMORS		56 10 66	62 11 73	58 14 72	61 17 78	

(HPT070)

BAIS3

APPENDIX L1

HISTOLOGICAL FINDINGS: NEOPLASTIC LESIONS: SUMMARY, RAT: MALE (2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj HISTOLOGICAL FINDINGS: NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1 : MALE

Group Name Control 1000 ppm 2000 ppm 4000 ppm Findings_ No. of animals on Study 50 50 50 [Integumentary system/appandage] skin/app <50> <50> ⟨50⟩ <50> squamous cell papilloma 1 (2%) 0 (0%) 1 (2%) 0 (0%) schwannoma 1 (2%) 0 (0%) 0 (0%) 0 (0%) keratoacanthoma 2 (4%) 4 (8%) 1 (2%) 2 (4%) subcutis <50> ⟨50⟩ ⟨50⟩ ⟨50⟩ fibroma 1 (2%) 4 (8%) 7 (14%) 12 (24%) Lipoma 0 (0%) 0 (0%) 4 (8%) 1 (2%) schwannoma 0 (0%) 1 (2%) 0 (0%) 0 (0%) fibrosarcoma 0 (0%) 0 (0%) 1 (2%) 0 (0%) schwannoma:malignant 0 (0%) 1 (2%) 1 (2%) 2 (4%) [Respiratory system] lung ⟨50⟩ ⟨50⟩ ⟨50⟩ ⟨50⟩ bronchiolar-alveolar adenoma 2 (4%) 0 (0%) 1 (2%) 1 (2%) bronchiolar-alveolar carcinoma 2 (4%) 1 (2%) 0 (0%) 1 (2%) [Hematopoietic system] bone marrow ⟨50⟩ ⟨50⟩ <50> osteoma 0 (0%) 1 (2%) 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(HPT085)

BAIS3

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

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : MALE

Organ		up Name of animals on Study	Control 50	1000 ppm 50	2000 ppm 50	4000 ppm 50
[Hematopoietio	c system]					
bone marrow	histiocytic sarcoma		<50> 0 (0%)	<50> 1 (2%)	<50> 2 (4%)	<50> 0 (0%)
lymph node	malignant lymphoma		<50> 1 (2%)	<50> 0 (0%)	<50> 2 (4%)	<50> 2 (4%)
spleen	hemangioma		<50> 1 (2%)	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)
	mononuclear cell leukemia		3 (6%)	3 (6%)	8 (16%)	4 (8%)
	hemangiosarcoma		0 (0%)	1 (2%)	0 (0%)	0 (0%)
[Circulatory s	system]					
heart	schwannoma		<50> 1 (2%)	<50> . 0 (0%)	<50> 2 (4%)	<50> 0 (0%)
[Digestive sys	stem]					
tongue	squamous cell papilloma		<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)
stomach	squamous cell papilloma		<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)	<50> 2 (4%)
	squamous cell carcinoma		1 (2%)	0 (0%)	0 (0%)	0 (0%)
	le i omyosarcoma		1 (2%)	0 (0%)	0 (0%)	0 (0%)
liver	hepatocellular adenoma		<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)	<50> 1 (2%)
(a) b(c)	a: Number of animals examined at the site b: Number of animals with neoplasm c:b/a*100					
(HPT085)						BAIS

: RAT F344/DuCrj

HISTOLOGICAL FINDINGS: NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1 SEX : MALE

ANIMAL

(HPT085)

Group Name Control 1000 ppm 2000 ppm 4000 ppm Organ_ Findings No. of animals on Study 50 [Digestive system] Liver <50> <50> <50> <50> histiocytic sarcoma 1 (2%) 0 (0%) 0 (0%) 0 (0%) hepatocellular carcinoma 1 (2%) 0 (0%) 1 (2%) 2 (4%) pancreas ⟨50⟩ <50> <50> <50> islet cell adenoma 6 (12%) 2 (4%) 4 (8%) 3 (6%) islet cell adenocarcinoma 0 (0%) 2 (4%) 0 (0%) 0 (0%) [Urinary system] kidney <50> <50> ⟨50⟩ (50) renal cell carcinoma 2 (4%) 0 (0%) 0 (0%) 0 (0%) nephroblastoma 0 (0%) 1 (2%) 0 (0%) 1 (2%) urin bladd <50> <50> <50> ⟨49⟩ transitional cell papilloma 0 (0%) 0 (0%) 1 (2%) 0 (0%) transitional cell carcinoma 0 (0%) 0 (0%) 1 (2%) 0 (0%) liposarcoma 0 (0%) 0 (0%) 0 (0%) 1 (2%) [Endocrine system] pituitary <50> <50> <50> ⟨50⟩ adenoma 18 (36%) 7 (14%) 10 (20%) 12 (24%) adenocarcinoma 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

ANIMAL : RAT F344/DuCrj

HISTOLOGICAL FINDINGS: NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1 SEX : MALE

Organ	Findings	Group Name Cor No. of animals on Study	ntro (L 50 	1000	ppm 50	2000	ppm 50	4000	ppm 50
(Endocrine sys	tem]									
thyroid	C-cell adenoma	5		50> 18%)	5	<48> (10%)	7	<49> (14%)	4	<50> (8%)
	follicular adenoma		0 (0%)	4	(8%)	0	(0%)	1	(2%)
	C-cell carcinoma	1	1 (2%)	0	(0%)	1	(2%)	2	(4%)
	follicular adenocarcinoma	2	2 (4%)	2	(4%)	0	(0%)	4	(8%)
adrena L	pheochromocytoma	3		50> 16%)	13	<50> (26%)	14	<50> (28%)	9	<50> (18%)
[Reproductive:	system]						•			
testis	interstitial cell tumor	45		49> 92%)	49	<50> (98%)	48	<50> (96%)	46	<50> (92%)
nammary gl	adenoma	1		50> 2%)	0	<50> (0%)	0	<50> (0%)	0	<50> (0%)
	fibroadenoma	1	1 (2%)	2	(4%)	3	(6%)	8	(16%)
	adenocarcinoma	1	1 (2%)	0	(0%)	0	(0%)	0	(0%)
orep/cligl	adenoma	C		50> 0%)	2	<50> (4%)	4	<50> (8%)	1	<50> (2%)
	adenocarcinoma	C	0 (0%)	1	(2%)	0	(0%)	0	(0%)
[Nervous system	n]									
brain	glioma	1		50> 2%)	0	<50> (0%)	1	<50> (2%)	0	<50> (0%)

ANIMAL : RAT F344/DuCrj

HISTOLOGICAL FINDINGS: NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1 SEX : MALE

PAGE: 5

Organ	Findings	Group Name No. of animals on Study	Control 50	1000 ppm 50	2000 ppm 50	4000 ppm 50
[Special sense	e organs/appandage]					
Zymbal gl	squamous cell carcinoma		<50> 1 (2%)	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)
Musculoskelet	tal system]					
oone	osteosarcoma		<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)
Body cavities	s]					
eritoneum	tumar:benign:NOS		<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)
	mesothelioma		3 (6%)	1 (2%)	0 (0%)	7 (14%)
	sarcoma:NOS		1 (2%)	0 (0%)	0 (0%)	0 (0%)
retroperit	schwannoma:malignant		<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)
(a) (c)	a: Number of animals examined at the site b: Number of animals with neoplasm c:b/a	* 100				
(IIPT085)				· · · · · · · · · · · · · · · · · · ·		

BAIS3

APPENDIX L2

HISTOLOGICAL FINDINGS: NEOPLASTIC LESIONS: SUMMARY, RAT: FEMALE (2-YEAR STUDY)

ANIMAL : RAT F344/DuC-j

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

REPORT TYPE : A1

SEX : FEMALE

Organ	Findings	Group Name No. of animals on Study	Control 50	1000 ppm 50	2000 ppm 50	4000 ppm 50	
[Integumentary	v system/appandage]						
skin/app	squamous cell papilloma		<50> 1 (2%)	<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)	
subcutis	fibroma		<50> 0 (0%)	<50> 2 (4%)	<50> 0 (0%)	<50> 1 (2%)	
	Lipoma		0 (0%)	1 (2%)	0 (0%)	0 (0%)	
	schwannoma		0 (0%)	0 (0%)	0 (0%)	1 (2%)	
[Respiratory s	system]						
nasal cavit	chondroma		<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)	
nasopharynx	squamous cell papilioma		<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)	
lung	bronchiolar-alveolar adenoma		<50> 2 (4%)	<50> 1 (2%)	<50> 2 (4%)	<50> 1 (2%)	
	adenosquamous carcinoma		1 (2%)	0 (0%)	0 (0%)	0 (0%)	
[Hematopoietic	system]						
lymph nade	malisnant Lymphoma		<50> 1 (2%)	<50> 2 (4%)	<50> 2 (4%)	<50> 2 (4%)	
spleen	mononuclear cell leukemia		<50> 2 (4%)	<50> 4 (8%)	<50> 8 (16%)	<50> 7 (14%)	
[Circulatory s	system]						
heart	schwannoma		<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)	
<a>><a> b (c)	a: Number of animals examined at the site b: Number of animals with neoplasm c:b/a*	100					

ANIMAL : RAT F344/DuCrj

HISTOLOGICAL FINDINGS: NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1

SEX : FEMALE

0rgan	Findings	Group Name Co No. of animals on Study	ontro	50	1000	ppm 50	2000	ppm 50	4000	ppm 50
[Digestive sy	stem]									
oral cavity	sarcoma:NOS			(50> (2 %)	0	<50> (0%)	0	<50> (0%)	0	<50> (0%)
stomach	squamous cell papilloma			(50> (2%)	1	<50> (2%)	0	<50> (0%)	0	<50> (0%)
liver	hepatocellular adenoma			(50> (4%)	0	<50> (0%)	0	<50> (0%)	3	<50> (6%)
	histiocytic sarcoma		0	(0%)	0	(0%)	1	(2%)	0	(0%)
pancreas	islet cell adenoma			(50> (2 %)	1	<50> (2%)	0	<50> (0%)	1	<50> (2%)
	islet cell adenocarcinoma		1	(2%)	0	(0%)	0	(0%)	0	(0%)
[Urinary syst	em]									
kidney	renal cell carcinoma			(50> (0 %)	0	<50> (0%)	0	<50> (0%)	1	<50> (2%)
urin bladd	transitional cell papilloma			(49) (4%)	0	<50> (0%)	0	<50> (0%)	0	<49> (0%)
[Endocrine sy	stemJ									
pituitary	adenoma	1		(50> (36 %)	28	<50> (56%)	24	<50> (48%)	19	<50> (38%)
	adenocareinoma		1	(2%)	1	(2%)	0	(0%)	0	(0%)
thyroid	C-cell adenoma			(49> (10%)	3	<50> (6%)	7	<50> (14%)	6	<50> (12%)
(a) b (c)	a: Number of animals examined at the site b: Number of animals with neoplasm c:b/a*	100								<u></u>
(HPT085)										

STUDY NO. : 0278 ANIMAL

: RAT F344/DuCri

HISTOLOGICAL FINDINGS: NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1 SEX

: FEMALE

Group Name 1000 ppm Control 2000 ppm 4000 ppm 0rgan Findings_ No. of animals on Study 50 50 50 50 [Endocrine system] thyroid (49) ⟨50⟩ ⟨50⟩ <50> follicular adenoma 0 (0%) 1 (2%) 1 (2%) 1 (2%) C-cell carcinoma 0 (0%) 1 (2%) 1 (2%) 1 (2%) follicular adenocarcinoma 2 (4%) 1 (2%) 0 (0%) 0 (0%) parathyroid <50> <50> <50> <50> adenoma 0 (0%) 1 (2%) 1 (2%) 0 (0%) adrenal <50> <50> <50> <50> pheochromocytoma 4 (8%) 2 (4%) 4 (8%) 2 (4%) cortical adenoma 1 (2%) 0 (0%) 0 (0%) 0 (0%) [Reproductive system] DUALA <50> <50> ⟨50⟩ <50> granulosa—theca cell tumor 1 (2%) 0 (0%) 0 (0%) 0 (0%) granulosa—theca cell tumor:malignant 0 (0%) 0 (0%) 0 (0%) 1 (2%) uterus <50> <50> ⟨50⟩ (50) leiomyoma 0 (0%) 0 (0%) 0 (0%) 1 (2%) endometrial stromal polyp 8 (16%) 11 (22%) 6 (12%) 9 (18%) adenocarcinoma 0 (0%) 0 (0%) 1 (2%) 0 (0%) Leiomyosarcoma 0 (0%) 0 (0%) 0 (0%) 1 (2%) (a) a : Number of animals examined at the site b (c) b: Number of animals with neoplasm c:b/a*100

⁽HPT085)

ANIMAL : RAT F344/DuCrj HISTOLOGICAL FINDINGS: NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1 : FEMALE

Group Name Control 1000 ppm 2000 ppm 4000 ppm Organ_ Findings No. of animals on Study 50 50 50 [Reproductive system] uterus <50> <50> <50> <50> endometrial stromal sarcoma 0 (0%) 0 (0%) 0 (0%) 2 (4%) vagina ⟨50⟩ <50> ⟨50⟩ ⟨50⟩ squamous cell papilloma 0 (0%) 0 (0%) 2 (4%) 0 (0%) mammary gl ⟨50⟩ <50> <50> <50> adenoma 0 (0%) 2 (4%) 1 (2%) 0 (0%) fibroadenoma 7 (14%) 7 (14%) 9 (18%) 14 (28%) adenocarcinoma 0 (0%) 2 (4%) 0 (0%) 1 (2%) prep/cligl <50> <50> <50> <50> squamous cell papilloma 1 (2%) 0 (0%) 0 (0%) 0 (0%) adenoma 1 (2%) 0 (0%) 0 (0%) 0 (0%) [Nervous system] brain <50> <50> <50> <50> glioma 1 (2%) 0 (0%) 0 (0%) 1 (2%) [Musculoskeletal system] bone <50> <50> <50> <50> osteosarcoma 0 (0%) 0 (0%) 1 (2%) 0 (0%) [Body cavities] adipose <50> <50> ⟨50⟩ Lipoma 0 (0%) 0 (0%) 0 (0%) 1 (2%) (a) a: Number of animals examined at the site b (c) b: Number of animals with neoplasm c:b/a*100

(HPT085)

APPENDIX M 1

NEOPLASTIC LESIONS - INCIDENCE AND STATISTICAL ANALYSIS, RAT: MALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

STUDY No. : 0278

: MALE PAGE: 1

Group Name	Control	1000 ppm	2000 ppm	4000 ppm	
	SITE : skin/appendage		111111111111111111111111111111111111111		
Tumor rate	TUMOR : keratoacanthoma				
Overall rates(a)	2/50(4.0)	4/50(8.0)	1/50(2.0)	2/50(4.0)	
Adjusted rates(b)	6.25	9.30	2.13	7.14	
Terminal rates(c) Statistical analysis	2/32(6.3)	4/43(9.3)	0/38(0.0)	2/28(7.1)	
Peto test					
Standard method(d)	P =				
Prevalence method(d)	P = 0.6142				
Combined analysis(d)	P =				
Cochran-Armitage test(e) Fisher Exact test(e)	P = 0.6865	P = 0.3389	P = 0.5000	P = 0.3088	
TIGICI BAGOL LOSE(O)		1 - 0.000	1 - 0.0000	1 - 0.0000	
	SITE : subcurtis				
	TUMOR : fibroma				
Tumor rate	1/50/ 0.0)	4/50(0.0)	7/50/ 14 0	10/50/ 04 0	
Overall rates(a) Adjusted rates(b)	1/50(2.0) 3.13	4/50(8.0) 9.30	7/50(14.0) 15.56	12/50(24.0) 36.67	
Terminal rates(c)	1/32(3.1)	4/43(9.3)	5/38(13.2)	10/28(35.7)	
Statistical analysis			,		
Peto test	P = 0.0799 ?				
Standard method(d) Prevalence method(d)	P = 0.0799 ; P = 0.0001**				
Combined analysis(d)	P < 0.0001**				
Cochran-Armitage test(e)	P = 0.0004**				
Fisher Exact test(e)		P = 0.1811	P = 0.0297*	P = 0.0009**	
part 400 141 14 14 14 14 14 14 14 14 14 14 14 14	OTMP				
	SITE : subcutis TUMOR : Lipoma				
Tumor rate	ronox · crpona				
Overall rates(a)	0/50(0.0)	0/50(0.0)	4/50(8.0)	1/50(2.0)	
Adjusted rates(b)	0.0	0.0	8.51	3.57	
Terminal rates(c) Statistical analysis	0/32(0.0)	0/43(0.0)	2/38(5.3)	1/28(3.6)	
Peto test					
Standard method(d)	P =				
Prevalence method(d)	P = 0.1510				
Combined analysis(d)	P =				
Cochran-Armitage test(e)	P = 0.3196				
Fisher Exact test(e)		P = 0.5000	P = 0.0587	P = 0.4999	

(HPT360A)

STUDY No. : 0278 ANIMAL : RAT F344/DuCrj SEX : MALE NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

				•	
Group Name	Control	1000 ppm	2000 ppm	4000 ppm	
	SITE : subcutis				
Tumor rate	TUMOR : fibroma, fibrosarcom	8.			
Overall rates(a)	1/50(2.0)	4/50(8.0)	8/50(16.0)	12/50(24.0)	
Adjusted rates(b)	3.13	9.30	17.78	36.67	
Terminal rates(c) Statistical analysis Peto test	1/32(3.1)	4/43(9.3)	6/38(15.8)	10/28(35.7)	
Standard method(d)	P = 0.0799 ?				
Prevalence method(d)	P = 0.0001**				
Combined analysis(d)	P < 0.0001**				
Cochran-Armitage test(e)	P = 0.0005**				
Fisher Exact test(e)		P = 0.1811	P = 0.0154*	P = 0.0009**	
	SITE : spleen				
	TUMOR : mononuclear cell le	ukemia			
Tumor rate					
Overall rates(a)	3/50(6.0)	3/50(6.0)	8/50(16.0)	4/50(8.0)	
Adjusted rates(b) Terminal rates(c)	2.56 0/32(0.0)	6.82 2/43(4.7)	10.53 4/38(10.5)	7.14	
Statistical analysis	0/32(0.0)	2/45(4.7)	4/36(10.5)	2/28(7.1)	
Peto test					
Standard method(d)	P = 0.2510				
Prevalence method(d)	P = 0.3346				
Combined analysis(d)	P = 0.2248				
Cochran-Armitage test(e) Fisher Exact test(e)	P = 0.5587	P = 0.3388	P = 0.0999	P = 0.4998	
	P***	1 - 0.5000	1 - 0.0000	1 - 0.4000	· · · · · · · · · · · · · · · · · · ·
	SITE : Liver				
	TUMOR : hepatocellular ader	oma,hepatocellular carcinoma			
Tumor rate	1/50/ 2.0)	0/50/ 0.0	0/50/ 4.0	0/50/ 0.0	
Overall rates(a) Adjusted rates(b)	1/50(2.0) 3.13	0/50(0.0) 0.0	2/50(4.0) 5.26	3/50(6.0)	
Terminal rates(c)	1/32(3.1)	0/43(0.0)	2/38(5.3)	10.71 3/28(10.7)	
Statistical analysis Peto test	-,,	-,(2, 30 (0.0)	0/20(10.7)	
Standard method(d)	P =				
Prevalence method(d)	P = 0.0371*				
Combined analysis(d)	P =				
Cochran-Armitage test(e) Fisher Exact test(e)	P = 0.1232	P = 0.4999	P = 0.5000	D - A 2000	
LISIO EXACT (BST(B)		r - v.4999	r = v.bvvv	P = 0.3086	

(HPT360A)

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STUDY No. : 0278
ANIMAL : RAT F344/DuCrj
SEX : MALE

Group Name	Control	1000 ppm	2000 ppm	4000 ppm	
	SITE : pancreas				
umor rate	TUMOR : islet cell adenoma				
Overall rates(a)	6/50(12.0)	2/50(4.0)	4/50(8.0)	3/50(6.0)	
Adjusted rates(b)	15.63	4.65	10.53	7.89	
Terminal rates(c)	5/32(15.6)	2/43(4.7)	4/38(10.5)	2/28(7.1)	
tatistical analysis	5,52(2505,	_,,	2,00(2010,	2/25(112/	
Peto test					
Standard method(d)	P =				
Prevalence method(d)	P = 0.7386				
Combined analysis(d)	P =				
Cochran-Armitage test(e)	P = 0.4405				
Fisher Exact test(e)		P = 0.1344	P = 0.3705	P = 0.2436	
`umor rate	SITE : pancreas TUMOR : islet cell adenoma,isle	t cell adenocarcinoma			
Overall rates(a)	6/50(12.0)	4/50(8.0)	4/50(8.0)	3/50(6.0)	
Adjusted rates(b)	15.63	6.98	10.53	7.89	
Terminal rates(c)	5/32(15.6)	3/43(7.0)	4/38(10.5)	2/28(7.1)	
Statistical analysis	0,02(2010,	0, 10 (1,0)	2,000 2000,	4,45(,11,	
Peto test					
Standard method(d)	P = 0.5972				
Prevalence method(d)	P = 0.7741				
Combined analysis(d)	P = 0.8052				
Cochran-Armitage test(e)	P = 0.3243				
Fisher Exact test(e)		P = 0.3705	P = 0.3705	P = 0.2436	
			·		
	SITE : pituitary gland				
Tunar rata	TUMOR : adenoma				
ïumor rate Overall rates(a)	18/50(36.0)	7/50(14.0)	10/50(20.0)	12/50(24.0)	
Adjusted rates(b)	35.56	16.28	18.75	37.93	
Terminal rates(c)	11/32(34.4)	7/43(16.3)	5/38(13.2)	10/28(35.7)	
Statistical analysis	11/00/ 01/1/	1/40(10.0)	0/00(10.2/	10/20(30.7)	
Peto test					
	P = 0.5900				
Standard method(d)	P = 0.7219				
Standard method(d) Prevalence method(d)					
Standard method(d) Prevalence method(d) Combined analysis(d)	P = 0.7419				
Prevalence method(d)	P = 0.7419 P = 0.4137				

STUDY No. : 0278 NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANIMAL : RAT F344/DuC-j
SEX : MALE

(HPT360A)

Group Name	Control	1000 ppm	2000 ppm	4000 ppm
	SITE : pituitary gland			
Tumor rate	TUMOR : adenoma, adenocarcinoma			
Overall rates(a)	19/50(38.0)	7/50(14.0)	10/50(20.0)	12/50(24.0)
Adjusted rates(b)	35.56	16.28	18,75	37.93
Terminal rates(c)	11/32(34.4)	7/43(16.3)	5/38(13.2)	10/28(35.7)
Statistical analysis Peto test			2, 22, 22.2,	10,400, 3000,
Standard method(d)	P = 0.7744			
Prevalence method(d)	P = 0.7219			
Combined analysis(d)	P = 0.7984			
Cochran-Armitage test(e)	P = 0.3137	D 0.005F	B 4 400=	
Fisher Exact test(e)		P = 0.0057**	P = 0.0385*	P = 0.0973
	SITE : thyroid TUMOR : C-cell adenoma			
Tumor rate	10.000 - C Catt add Colla			
Overall rates(a)	9/50(18.0)	5/48(10.4)	7/49(14.3)	4/50(8.0)
Adjusted rates(b)	21.95	10.64	17.50	9.76
Terminal rates(c)	6/32(18.8)	4/43(9.3)	6/37(16.2)	2/28(7.1)
Statistical analysis				
Peto test				
Standard method(d) Prevalence method(d)	P =			
Combined analysis(d)	P = 0.9082 P =			
Cochran-Armitage test(e)	P = 0.2001			
Fisher Exact test(e)	1 = 0.2001	P = 0.2174	P = 0.4104	P = 0.1169
		1 0,51(1	1 - 0.4104	1 - 0.1108
	SITE : thyroid TUMOR : follicular adenoma			
Tumor rate	Tonon . Tottscutal adolicila			
Overall rates(a)	0/50(0.0)	4/48(8.3)	0/49(0.0)	1/50(2.0)
Adjusted rates(b)	0.0	9.30	0.0	3.03
Terminal rates(c)	0/32(0.0)	4/43(9.3)	0/37(0.0)	0/28(0.0)
Statistical analysis		•		• • • • • •
Peto test	_			
Standard method(d)	P =			
Prevalence method(d)	P = 0.5241			
Combined analysis(d)	P =			
Cochran-Armitage test(e) Fisher Exact test(e)	P = 0.8119	P = 0.0539	P = 0.5000	P = 0.4999
1401 1031(8)		0.0000	1 - 0.0000	r = 0.4888

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ANIMAL : RAT F344/DuCrj
SEX : MALE

STUDY No. : 0278

Group Name	Control	1000 ppm	2000 ppm	4000 ppm	
	SITE : thyroid				
_	TUMOR : follicular adenocar	cinoma			
fumor rate	0/50/ 4.03	0/40/ 4.0	0/40/ 0.0	. (50 (
Overall rates(a) Adjusted rates(b)	2/50(4.0) 5.56	2/48(4.2)	0/49(0.0)	4/50(8.0)	
Terminal rates(c)	1/32(3.1)	2.33 1/43(2.3)	0.0 0/37(0.0)	14.29	
Statistical analysis	1/02(0.1)	1/40(2.5)	0/3/(0.0)	4/28(14.3)	
Peto test					
Standard method(d)	P = 0.5868				
Prevalence method(d)	P = 0.0671				
Combined analysis(d)	P = 0.1126				
Cochran-Armitage test(e)	P = 0.3381				
Fisher Exact test(e)		P = 0.3243	P = 0.2525	P = 0.3389	
	SITE : thyroid				
	TUMOR : C-cell adenoma, C-ce	all carcinoma			
lumor rate					
Overall rates(a)	10/50(20.0)	5/48(10.4)	8/49(16.3)	6/50(12.0)	
Adjusted rates(b)	21.95	10.64	20.00	13.95	
Terminal rates(c)	6/32(18.8)	4/43(9.3)	7/37(18.9)	3/28(10.7)	
Statistical analysis Peto test					
Standard method(d)	P =				
Prevalence method(d)	P = 0.7351				
Combined analysis(d)	P =				
Cochran-Armitage test(e)	P = 0.4227				
Fisher Exact test(e)		P = 0.1501	P = 0.4166	P = 0.2071	
		141-14-14-14-14-14-14-14-14-14-14-14-14-			
	SITE : thyroid TUMOR : follicular adenoma	follion or odenovaniano			
Tumor rate	TOHOR . TOTETCUTAL ACHICINA	TUTETCUEAL AGENDOALCTHUMA			
Overall rates(a)	2/50(4.0)	6/48(12.5)	0/49(0.0)	5/50(10.0)	
Adjusted rates(b)	5.56	11.63	0.0	15.15	
Terminal rates(c)	1/32(3.1)	5/43(11.6)	0/37(0.0)	4/28(14.3)	
Statistical analysis		· ·	• • •	. (,	
Peto test					
Standard method(d)	P = 0.5868				
Prevalence method(d)	P = 0.1455				
Combined analysis(d)	P = 0.1943				
Cochran-Armitage test(e) Fisher Exact test(e)	P = 0.5413	P = 0.1213	P = 0.2525	P = 0.2181	
		P = D 1213	V ≈ 0. 7575	D = 0 0101	

STUDY No. : 0278
ANIMAL : RAT F344/DuCrj
SEX : MALE PAGE: 6

Group Name	Control	1000 ppm	2000 ppm	4000 ppm	
	SITE : adrenal gland				
	TUMOR : pheochromocytoma				
Cumor rate					
Overall rates(a)	8/50(16.0)	13/50(26.0)	14/50(28.0)	9/50(18.0)	
Adjusted rates(b)	18.18	27.27	31.71	24.24	
Terminal rates(c)	5/32(15.6)	11/43(25.6)	11/38(28.9)	5/28(17.9)	
Statistical analysis					
Peto test					
Standard method(d)	P =				
Prevalence method(d)	P = 0.4229				
Combined analysis(d)	P =				
Cochran-Armitage test(e)	P = 1.0000				
Fisher Exact test(e)		P = 0.1634	P = 0.1137	P = 0.4995	
	SITE : testis				
_	TUMOR : interstitial cell tumor				
Tumor rate	45 (40 (04 0)	10/20/ 00 0	40 (50 (00 0)	10/10/ 00 0	
Overall rates(a)	45/49(91.8)	49/50(98.0)	48/50 (96.0)	46/50(92.0)	
Adjusted rates(b)	97.30	100.00	100.00	97.56	
Terminal rates(c)	31/32(96.9)	43/43(100.0)	38/38(100.0)	27/28(96.4)	
Statistical analysis Peto test					
Standard method(d)	P =				
Prevalence method(d)	P = 0.4959				
Combined analysis(d)	P =				
Cochran-Armitage test(e)	P = 0.7285				
Fisher Exact test(e)	1 - 0,7200	P = 0.1748	P = 0.3292	P = 0.3459	
				. 0.0200	
	SITE : mammary gland				
	TUMOR : fibroadenoma				
Tumor rate	1/50/ 0.0)	9/50/ 4.2	0/50/ 0.0	0/50/ +0 0	
Overall rates(a)	1/50(2.0)	2/50(4.0)	3/50(6.0)	8/50(16.0)	
Adjusted rates(b)	3.13	4.65	6.12	25.00	
Terminal rates(c)	1/32(3.1)	2/43(4.7)	2/38(5.3)	7/28(25.0)	
Statistical analysis					
Peto test	P = 0 0099				
Standard method(d)	P = 0.0923				
Prevalence method(d)	P = 0.0020**				
Combined analysis(d) Cochran-Armitage test(e)	P = 0.0007** P = 0.0037**				
Fisher Exact test(e)	r - v.VV0/**	P = 0.5000	P = 0.3086	D = 0.0154±	
risite Exact Test(e)		r = 0.0000	r = v.3080	P = 0.0154*	

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STUDY No. : 0278 ANIMAL : RAT F344/DuC-j SEX : MALE

Group Name	Control	1000 ppm	2000 ppm	4000 ppm	
	SITE : mammary gland				
'umor rate	TUMOR : adenoma, fibroadenoma				
Overall rates(a)	2/50(4.0)	2/50(4.0)	3/50(6.0)	8/50(16.0)	
Adjusted rates(b)	6.25	4.65	6.12	25.00	
Terminal rates(c)	2/32(6.3)	2/43(4.7)	2/38(5.3)	7/28(25.0)	
tatistical analysis Peto test					
Standard method(d)	P = 0.0923				
Prevalence method(d)	P = 0.0068**				
Combined analysis(d)	P = 0.0026**				
Cochran-Armitage test(e)	P = 0.0126*				
Fisher Exact test(e)		P = 0.3088	P = 0.4999	P = 0.0458*	
	SITE : mammary gland				
_	TUMOR : adenoma, fibroadenoma, adenoc	arcinoma			
umor rate	0/50/ 0.0)	0/50/ 4.0)	0/50/ 0.0	0/20/ 10 0)	
Overall rates(a) Adjusted rates(b)	3/50(6.0) 6.25	2/50(4.0) 4.65	3/50(6.0)	8/50(16.0)	
Terminal rates(c)	2/32(6.3)	2/43(4.7)	6.12 2/38(5.3)	25.00 7/28(25.0)	
Statistical analysis	2,02(0.0,	2/10(11.)	2700(0.0)	1720(20.0)	
Peto test					
Standard method(d)	P = 0.3854		· ·		
Prevalence method(d) Combined analysis(d)	P = 0.0068** P = 0.0086**				
Cochran-Armitage test(e)	P = 0.0086** P = 0.0345*				
Fisher Exact test(e)	1 - 0.0040*	P = 0.4999	P = 0.3388	P = 0.0999	
· · · · · · · · · · · · · · · · · · ·		territoria de la constanti de			
	SITE : preputjal/clitoral gland				
	TUMOR : adenoma				
fumor rate					
Overall rates(a)	0/50(0.0)	2/50(4.0)	4/50(8.0)	1/50(2.0)	
Adjusted rates(b)	0.0	4.65	9.76	3.57	
Terminal rates(c) Statistical analysis	0/32(0.0)	2/43(4.7)	3/38(7.9)	1/28(3.6)	
Peto test					
Standard method(d)	P =				
Prevalence method(d)	P = 0.2418				
Combined analysis(d)	P =				
Cochran-Armitage test(e)	P = 0.6489				
Fisher Exact test(e)		P = 0.2475	P = 0.0587	P = 0.4999	

SEX

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANIMAL : RAT F344/DuCrj : MALE

Group Name	Control	1000 ppm	2000 ppm	4000 ppm	
	SITE : preputial/clitoral gland				
B	TUMOR : adenoma, adenocarcinoma				
Numor rate Overall rates(a)	0/50(0.0)	3/50(6.0)	4/50(9.0)	1/50/ 0.0)	
Adjusted rates(b)	0.0	6.98	4/50(8.0) 9.76	1/50(2.0) 3.57	
Terminal rates(c)	0/32(0.0)	3/43(7.0)	3/38(7.9)	1/28(3.6)	
Statistical analysis	0,02(000)	5, 15(1,0)	0,00(1.0)	1,20(0.0)	
Peto test					
Standard method(d)	P =				
Prevalence method(d)	P = 0.3085				
Combined analysis(d)	P =				
Cochran-Armitage test(e)	P = 0.8073	D 0 1010	D 0.0505		
Fisher Exact test(e)		P = 0.1212	P = 0.0587	P = 0.4999	
	SITE : peritoneum				
	TUMOR : mesothelioma				
ľumor rate					
Overall rates(a)	3/50(6.0)	1/50(2.0)	0/50(0.0)	7/50(14.0)	
Adjusted rates(b)	5.13	0.0	0.0	14.29	
Terminal rates(c)	1/32(3.1)	0/43(0.0)	0/38(0.0)	4/28(14.3)	
Statistical analysis					
Peto test Standard method(d)	P = 0.0960				
Prevalence method(d)	P = 0.0568				
Combined analysis(d)	P = 0.0198*				
Cochran-Armitage test(e)	P = 0.0409*				
COCH alt will rase feet (a)	1 - 0.0400**				

(HPT360A)

BAIS3

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Standard method : Death analysis

Prevalence method: Incidental tumor test

Combined analysis : Death analysis + Incidental tumor test

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

⁽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.

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

^{?:} The conditional probabities of the largest and smallest possible out comes can not estimated or this P-value is beyond the estimated P-value.

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

APPENDIX M 2

NEOPLASTIC LESIONS - INCIDENCE AND STATISTICAL ANALYSIS, RAT: FEMALE $(\hbox{2-YEAR STUDY})$

ANIMAL : RAT F344/DuCrj SEX : FEMALE

STUDY No. : 0278

Group Name	Control	1000 ppm	2000 ppm	4000 ppm	
	SITE : lung	r adenoma, adenosquamous carcinoma			
mor rate					
verall rates(a) djusted rates(b)	3/50(6.0) 6.67	1/50(2.0) 2.50	2/50(4.0) 4.08	1/50(2.0)	
rminal rates(c) tistical analysis	3/45(6.7)	1/40(2.5)	1/43(2.3)	3.03 0/30(0.0)	
eto test Standard method(d)	P =				
Prevalence method(d) Combined analysis(d)	P = 0.7590 P =				
ochran—Armitage test(e)	P = 0.3979				
sher Exact test(e)		P = 0.3086	P = 0.4999	P = 0.3086	
	SITE : spleen TUMOR : mononuclear cell le	oukemia			
nor rate verall rates(a)	2/50(4.0)	4/50(8.0)	8/50(16.0)	7/50(14.0)	
djusted rates(b)	2.22	7.50	9.30	10.00	
erminal rates(c) atistical analysis eto test	1/45(2.2)	3/40(7.5)	4/43(9.3)	3/30(10.0)	
Standard method(d) Prevalence method(d)	P = 0.0375* P = 0.1001				
Combined analysis(d)	P = 0.0151*				
ochran-Armitage test(e) isher Exact test(e)	P = 0.0793	P = 0.3389	P = 0.0458*	P = 0.0798	
	SITE : liver TUMOR : hepatocellular ader	nome.			
mor rate					
verall rates(a) diusted rates(b)	2/50(4.0) 4.44	0/50(0.0) 0.0	0/50(0.0)	3/50(6.0)	
erminal rates(c)	2/45(4.4)	0/40(0.0)	0.0 0/43(0.0)	9.68 2/30(6.7)	
atistical analysis eto test		-, ,	0, 10(0.0)	2,000 0.17	
Standard method(d)	P =				
Prevalence method(d)	P = 0.1002				
Combined analysis(d) ochran—Armitage test(e)	P = P = 0.3196				
isher Exact test(e)	. 0.0100	P = 0.2475	P = 0.2475	P = 0.4999	

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANIMAL : RAT F344/DuC-j SEX : FEMALE

Group Name	Control	1000 ppm ,	2000 ppm	4000 ppm
	SITE : liver			
P	TUMOR : hepatocellular adend	ma,hepatocellular carcinoma		
ſumor rate Overall rates(a)	2/50(4.0)	0/50(0.0)	0/50(0.0)	3/50(6.0)
Adjusted rates(b)	4.44	0.0	0.0	9.68
Terminal rates(c)	2/45(4.4)	0/40(0.0)	0/43(0.0)	2/30(6.7)
Statistical analysis Peto test	2, 10 (11.1)	0,10(0,0)	0, 10(0.0)	2/00(0.7/
Standard method(d)	P =			
Prevalence method(d)	P = 0.1002			
Combined analysis(d)	P =			
Cochran-Armitage test(e)	P = 0.3196			
Fisher Exact test(e)		P = 0.2475	P = 0.2475	P = 0.4999
Tumor rate Overall rates(a)	SITE : pituitary gland TUMOR : adenoma 18/50(36.0)	28/50(56.0)	24/50(48.0)	19/50(38.0)
Adjusted rates(b)	37.78	53.19	51.16	42.42
Terminal rates(c) Statistical analysis	17/45(37.8)	19/40(47.5)	22/43(51.2)	12/30(40.0)
Peto test Standard method(d) Prevalence method(d) Combined analysis(d) Cochran-Armitage test(e)	P = 0.1991 P = 0.5048 P = 0.3817 P = 0.7183			
Fisher Exact test(e)		P = 0.0353*	P = 0.1558	P = 0.4991
Direct water	SITE : pituitary gland TUMOR : adenoma,adenocarcino	oxna		
Tumor rate Overall rates(a)	19/50(38.0)	29/50(58.0)	24/50(48.0)	10/50/ 90 0
Adjusted rates(b)	37.78	29/50(58.0) 55.32	24/50(48.0) 51.16	19/50(38.0) 42.42
Terminal rates(c)	17/45(37.8)	20/40(50.0)	22/43(51.2)	12/30(40.0)
Statistical analysis Peto test	2., 10 (0.10)	20, 10 (00.0)	20/ 10\ U1.2)	12/30(40.0)
Standard method(d)	P = 0.3387			
Prevalence method(d)	P = 0.5659			
Combined analysis(d)	P = 0.4988			
Cochran-Armitage test(e)	P = 0.5485	D 0.050		
Fisher Exact test(e)		P = 0.0356*	P = 0.2101	P = 0.4173

(HPT360A)

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANIMAL : RAT F344/DuCrj SEX : FEMALE

Group Name 2000 ppm Control 1000 ppm 4000 ppm SITE : thyroid TUMOR : C-cell adenoma Tumor rate Overall rates(a) 5/49(10.2) 3/50(6.0) 7/50(14.0) 6/50(12.0) Adjusted rates(b) 11.36 7.50 16,28 15.00 Terminal rates(c) 5/44(11.4) 3/40(7.5) 7/43(16.3) 3/30(10.0) Statistical analysis Peto test Standard method(d) P = ----Prevalence method(d) P = 0.1628Combined analysis(d) Cochran-Armitage test(e) P = 0.5255Fisher Exact test(e) P = 0.3462P = 0.3945P = 0.4852SITE : thyroid TUMOR : C-cell adenoma, C-cell carcinoma Tumor rate Overall rates(a) 5/49(10.2) 4/50(8.0) 8/50(16.0) 7/50(14.0) Adjusted rates(b) 11.36 10.00 18.60 15.00 Terminal rates(c) 5/44(11.4) 4/40(10.0) 8/43(18.6) 3/30(10.0) Statistical analysis Peto test Standard method(d) P = 0.1069Prevalence method(d) P = 0.1758Combined analysis(d) P = 0.1069Cochran-Armitage test(e) P = 0.3937Fisher Exact test(e) P = 0.4873P = 0.2902P = 0.3945SITE : adrenat gland TUMOR : pheochromocytoma Tumor rate Overall rates(a) 4/50(8.0) 2/50(4.0) 4/50(8.0) 2/50(4.0) Adjusted rates(b) 8.89 5,00 8.51 4.76 Terminal rates(c) 4/45(8.9) 2/40(5.0) 3/43(7.0) 1/30(3.3) Statistical analysis Peto test Standard method(d) P = -----Prevalence method(d) P = 0.6688Combined analysis(d) Cochran-Armitage test(e) P = 0.5459Fisher Exact test(e) P = 0.3389P = 0.3573P = 0.3389

(HPT360A)

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

STUDY No. : 0278
ANIMAL : RAT F344/DuCrj
SEX : FEMALE

Group Name	Control	1000 ppm	2000 ppm	4000 ppm	
	SITE : uterus				
Tumor rate	TUMOR : endometrial stromal pol	ур			
Overall rates(a)	8/50(16.0)	11/50(22.0)	6/50(12.0)	9/50(18.0)	
Adjusted rates(b)	17.39	21.28	13.95	20.00	
Terminal rates(c)	7/45(15.6)	8/40(20.0)	6/43(14.0)	6/30(20.0)	
Statistical analysis					
Peto test Standard method(d)	P = 0.0152*				
Prevalence method(d)	P = 0.6589				
Combined analysis(d)	P = 0.3162				
Cochran-Armitage test(e)	P = 0.9493				
Fisher Exact test(e)		P = 0.3059	P = 0.3875	P = 0.4995	
Tumor rate	SITE : uterus TUMOR : endometrial stromal sar	rcoma,leiomyosarcoma			
Overall rates(a)	0/50(0.0)	0/50(0.0)	0/50(0.0)	3/50(6.0)	
Adjusted rates(b)	0.0	0.0	0.0	0.0	
Terminal rates(c)	0/45(0.0)	0/40(0.0)	0/43(0.0)	0/30(0.0)	
Statistical analysis Peto test					
Standard method(d)	P = 0.0034**?				
Prevalence method(d)	P =				
Combined analysis(d)	P = 0.0034**?				
Cochran-Armitage test(e)	P = 0.0079**	D 0 5000			
Fisher Exact test(e)	`	P = 0.5000	P = 0.5000	P = 0.1212	
Timor poto	SITE : mammary gland TUMOR : fibroadenoma				-
Tumor rate Overall rates(a)	7/50(14.0)	7/50(14.0)	9/50(18.0)	14/50(28.0)	
Adjusted rates(b)	15.56	15.00	20.93	43.33	
Terminal rates(c)	7/45(15.6)	6/40(15.0)	9/43(20.9)	13/30(43.3)	
Statistical analysis Peto test	·		-,,	20, 20, 20, 20, 20, 20, 20, 20, 20, 20,	
Standard method(d)	P =				
Prevalence method(d)	P = 0.0029**				
Combined analysis(d)	P =				
Cochran-Armitage test(e) Fisher Exact test(e)	P = 0.0454*	P = 0.3866	D = 0 9099	D A ACOO	
FISHER EXACT TEST(6)		r = 0.0000	P = 0.3932	P = 0.0699	

(HPT360A)

ANIMAL : RAT F344/DuC-j

SEX : FEMALE

Group Name Control 1000 ppm 2000 ppm 4000 ppm SITE : mammary gland TUMOR : adenoma, fibroadenoma Tumor rate Overall rates(a) 7/50(14.0) 8/50(16.0) 10/50(20.0) 14/50(28.0) Adjusted rates(b) 15.56 17.50 23.26 43.33 Terminal rates(c) 7/45(15.6) 7/40(17.5) 10/43(23.3) 13/30(43.3) Statistical analysis Peto test Standard method(d) P = ----Prevalence method(d) P = 0.0035**Combined analysis(d) P = ----Cochran-Armitage test(e) P = 0.0574Fisher Exact test(e) P = 0.4996P = 0.2980P = 0.0699SITE : mammary gland TUMOR : adenoma, fibroadenoma, adenocarcinoma Tumor rate Overall rates(a) 7/50(14.0) 9/50(18.0) 10/50(20.0) 14/50(28.0) Adjusted rates(b) 15.56 18,18 23.26 43.33 Terminal rates(c) 7/45(15.6) 7/40(17.5) 10/43(23.3) 13/30(43.3) Statistical analysis Peto test Standard method(d) P = 0.5814Prevalence method(d) P = 0.0038**Combined analysis(d) P = 0.0056**Cochran-Armitage test(e) P = 0.0730Fisher Exact test(e) P = 0.3932P = 0.2980P = 0.0699

BAIS3

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Standard method : Death analysis

Prevalence method: Incidental tumor test

Combined analysis: Death analysis + Incidental tumor test

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

⁽HPT360A)

⁽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.

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

^{?:} The conditional probabities of the largest and smallest possible out comes can not estimated or this P-value is beyond the estimated P-value.

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

APPENDIX N 1

HISTOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY, RAT: MALE: ALL ANIMALS (2-YEAR STUDY)

HISTOLOGICAL FINDINGS: METASTASIS OF TUMOR (SUMMARY)

ANIMAL : RAT F344/DuCrj

ALL ANIMALS (0-105W)

REPORT TYPE : A1

(JPT150)

EX : MALE

Group Name Control 1000 ppm 2000 ppm 4000 ppm No. of Animals on Study 50 50 50 Findings [Integumentary system/appandage] subcutis ⟨50⟩ ⟨50⟩ ⟨50⟩ <50> leukemic cell infiltration [Respiratory system] nasal cavit <50> <50> <50> ⟨50⟩ leukemic cell infiltration 1 4 lung <50> <50> <50> <50> leukemic cell infiltration 2 2 3 metastasis:liver tumor 0 0 metastasis:thyroid tumor metastasis:peritoneum tumor metastasis:subcutis tumor metastasis:bone tumor [Hematopoietic system] bone marrow ⟨50⟩ <50> ⟨50⟩ <50> leukemic cell infiltration 2 5 3 lymph node <50> <50> <50> <50> leukemic cell infiltration 2 1 2 metastasis:bone marrow tumor 0 1 0 spleen <50> ⟨50⟩ <50> <50> leukemic cell infiltration 1 1 .0 <a>> a: Number of animals examined at the site b b: Number of animals with Lesion

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY) ALL ANIMALS (0-105W) $\,$

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE

Organ		Group Name Control No. of Animals on Study 50	1000 ppm 50	2000 ppm 50	4000 ppm 50
[Nematopoietio	c system]				
spleen	metastasis:liver tumor	<50> 1	<50> 0	<50> 0	<50> 0
	metastasis:peritoneum tumor	0	0	0	2
	metastasis:bone marrow tumor	0	1	0	0
[Circulatory s	system]				
heart	leukemic cell infiltration	<50> 0	<50> 0	<50> 0	<50> 1
[Digestive sy	stem]				
salivary gl	leukemic cell infiltration	<50> 0	<50> 0	<50> 1	<50> 0
	metastasis:peritoneum tumor	0	0	0	1
stomach	leukemic cell infiltration	<50> 0	<50> 0 .	<50> 1	<50> 0
	metastasis:peritoneum tumor	1	0	0	2
small intes	leukemic cell infiltration	<50> 0	<50> 0	<50> 1	<50> 0
	metastasis:peritoneum tumor	1	0	0	0
large intes	leukemic cell infiltration	<50> 0	<50> 0	<50> 1	<50> 1
	metastasis:peritoneum tumor	1	0	0	0
⟨a⟩ b	a: Number of animals examined at the s b: Number of animals with lesion	te			

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)

PAGE: 3

BAIS3

: RAT F344/DuCrj

ALL ANIMALS (0-105W)

REPORT TYPE : A1 SEX : MALE

ANIMAL

(JPT150)

1000 ppm Group Name Control 2000 ppm 4000 ppm No. of Animals on Study 50 50 50 50 Findings_ [Digestive system] liver ⟨50⟩ <50> <50> (50) leukemic cell infiltration 2 3 8 4 metastasis:peritoneum tumor 0 0 metastasis:bone marrow tumor 0 1 0 0 pancreas ⟨50⟩ <50> <50> ⟨50⟩ leukemic cell infiltration 0 0 0 metastasis:peritoneum tumor 0 0 5 [Urinary system] kidney <50> ⟨50⟩ <50> <50> leukemic cell infiltration 4 1 metastasis:peritoneum tumor 0 0 1 urin bladd <50> ⟨50⟩ <50> <49> leukemic cell infiltration [Endocrine system] pituitary <50> ⟨50⟩ (50) <50> leukemic cell infiltration 1 0 thyroid ⟨50⟩ <50> ⟨50⟩ ⟨50⟩ leukemic cell infiltration 0 0 0 adrenal <50> ⟨50⟩ ⟨50⟩ <50> leukemic cell infiltration metastasis:liver tumor 1 0 0 0 (a) a: Number of animals examined at the site b: Number of animals with lesion

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

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE

Organ		Group Name Control No. of Animals on Study 50	1000 ppm 50	2000 ppm 50	4000 ppm 50
[Endocrine sy	vstem]				
adrena l	metastasis:peritoneum tumor	<50> 0	<50> 0	<50> 0	<50> 1
[Reproductive	e system]				
testis	leukemic cell infiltration	<50> 2	<50> 0	<50> 3	<50> 1
epididymis	leukemic cell infiltration	<50> 0	<50> 0	<50> 1	<50> 0
prostate	leukemic cell infiltration	<50> 0	<50> 0	<50> 2	<50> 0
[Nervous syst	tem]				
brain	leukemic coll infiltration	<50> 1	<50> 1	<50> 1	<50> 0
	metastasis:pituitary tumor	1	0	0	0
spinal cord	leukemic cell infiltration	<50> 1	<50> 0	<50> 0	<50> 0
[Special sens	se organs/appandage]				
Harder gl	leukemic cell infiltration	<50> 0	<50> 0	<50> 0	<50> 1
[Body cavitie	es]				
pleura	metastasis:subcutis tumor	<50> 0	<50> 0	<50> 1	<50> 0
(a) b	a: Number of animals examined at the s b: Number of animals with lesion	ite			
(JPT150)					BA

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : MALE

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Organ		Group Name No. of Animals on Study	Control 50	1000 ppm 50	2000 ppm 50	4000 ppm 50
Body cavities	s]					
oleura	metastasis:lung tumor		<50> 1	<50> 0	<50> 0	<50> 0
ediastinum	metastasis:peritoneum tumor		<50> 1	<50> 0	<50> 0	<50> 0
etroperit	leukemic cell infiltration		<50> 0	<50> 0	<50>	<50> 0
a > b	a: Number of animals examined at the si b: Number of animals with lesion	te				
JPT150)				*		

BAIS3

APPENDIX N 2

HISTOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY, RAT: MALE: DEAD AND MORIBUND ANIMALS (2-YEAR STUDY)

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

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : MALE

Organ	Findings	Group Name Control No. of Animals on Study 18	1000 ppm 7	2000 ppm 12	4000 ppm 22
[Integumentary	y system/appandage}		1,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
subcutis	leukemic cell infiltration	<18> 0	< 7> 0	<12> 1	<22> 0
[Respiratory s	system]				
nasal cavit	leukemic cell infiltration	<18>	< 7>	<12> 3	<22> 0
lung	leukemic cell infiltration	<18> 2	< 7>	<12> 2	<22> 2
	metastasis:liver tumor	1	0	0	0
	metastasis:peritoneum tumor	1	0	0	1
	metastasis:subcutis tumor	0	0	1	1
[Hematopoietic	c system]	-			
bone marrow	leukemic cell infiltration	<18>	< 7> 0	<12> 4	<22> 2
lymph nade	- Leukemic cell infiltration	<18> 2	< 7> 0	<12>	<22> 1
	metastasis:bone marrow tumor	0	1	0	0
spleen	leukemic cell infiltration	<18>	< 7> 0	<12>	<22> 0
	metastasis:liver tumor	1	0	0	0
	metastasis:peritoneum tumor	0	0	0	1
(a > b	a : Number of animals examined at b : Number of animals with lesion	the site			

HISTOLOGICAL FINDINGS: METASTASIS OF TUMOR (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : MALE

STUDY NO. : 0278

)rgan	Findings	Group Name No. of Animals on Study	Control 18	1000 ppm 7	2000 ppm 12	4000 ppm 22
[Hematopoieti	c system]					
pleen	metastasis:bone marrow tumor		<18> 0	< 7> 1	<12> 0	<22> 0
Circulatory	system]					
eart	leukemic cell infiltration		<18> 0	< 7> 0	<12> 0	<22> 1
Digestive sy	stem]					
alivary gl	leukemic cell infiltration		<18> 0	< 7> 0	<12>	<22>
tomach	leukemic cell infiltration		<18> 0	< 7> 0	<12>	<222>
	metastasis:peritoneum tumor		1	0	0	1
mall intes	leukemic cell infiltration		<18> 0	< 7> 0	<12>	<22>
	metastasis:peritoneum tumor		1	0	0	0
arge intes	leukemic cell infiltration		<18> 0	< 7>	<12>	<222>
	metastasis:peritoneum tumor		1	0	0	0
iver	leukemic cell infiltration		<18> 2	< 7>	<12> 5	<22> 3
	metastasis:bone marrow tumor		0	1	0	0
ancreas	leukemic cell infiltration		<18>	< 7> 0	<12>	<22> 0

(JPT150)

BAIS3

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

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE

Organ		Group Name Control No. of Animals on Study 18	1000 ppm 7	2000 ppm 12	4000 ppm 22
[Digestive sy	vstem]				
pancreas	metastasis:peritoneum tumor	<18> 2	< 7> 0	<12> 0	<22> 3
[Urinary syst	tem]				
kidney	leukemic cell infiltration	<18> 0	< 7> 1	<12> 3	<22> 1
	metastasis:peritoneum tumor	0	0	0	1
urin bladd	leukemic cell infiltration	<18> 1	< 7> 0	<12>	<22> 0
[Endocrine sy	vstem]				
pituitary	leukemic cell infiltration	<18> 1	< 7> 1	<12>	<22> 0
thyroid	leukemic cell infiltration	<18> 0	< 5> 0	<12> 0	<22> 1
adrenal	leukemic cell infiltration	<18> 1	< 7>	<12> 1	<22> 0
	metastasis:liver tumor	1	0	0	0
	metastasis:peritoneum tumor	0	0	0	1
(Reproductive	e system]				
testis	leukemic cell infiltration	<18> 2	< 7> 0	<12> 3	<22> 0
√a> b	a: Number of animals examined at the sib: Number of animals with lesion	ite			
(JPT150)					BAISS

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : MALE

Organ	Findings	Group Name Control No. of Animals on Study 18	1000 ppm 7	2000 ppm 12	4000 ppm 22
[Reproductive	system]				
epididymis	leukemic cell infiltration	<18> 0	< 7> 0	<12> 1	<22> 0
prostate	leukemic cell infiltration	<18> 0	< 7> 0	<12> 1	<22> 0
[Nervous syste	em]				
brain	leukemic cell infiltration	<18>	< 7> 1	<12>	<22> 0
	metastasis:pituitary tumor	1	0	0	0
spinal cord	leukemic cell infiltration	<18> 1	< 7> 0	<12> 0	<22> 0
[Special sense	e organs/appandage]				
Harder gl	leukemic cell infiltration	<18> 0	< 7> 0	<12> 0	<22> 1
[Body cavities	s]				
pleura	metastasis:subcutis tumor	<18>	< 7> 0	<12>	<22> 0
	metastasis:lung tumor	1	0	0	.0
mediastinum	metastasis:peritoneum tumor	<18>	< 7>	<12> 0	<22>
(a)	a: Number of animals examined at the b: Number of animals with lesion	site			

APPENDIX N 3

HISTOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY, RAT: MALE: SACRIFICED ANIMALS (2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 : MALE

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

Organ		Group Name Control No. of Animals on Study 32	1000 ppm 43	2000 ppm 38	4000 ppm 28
[Respiratory s	system]				
nasal cavit	leukemic cell infiltration	<32> 0	<43> 0	<38> 1	<28> 0
lung	leukemic cell infiltration	<32> 0	<43>	<38>	<28> 0
	metastasis:thyroid tumor	1	0	0	1
	metastasis:bone tumor	0	0	1	0
[Hematopoietic	system]				
bone marrow	leukemic cell infiltration	<32> 0	<43> 0	<38>	<28> 1
lymph node	leukemic cell infiltration	<32> 0	<43> 1	<38>	<28> 0
spleen	metastasis:peritoneum tumor	<32> 0	<43> 0	<38> 0	<28> 1
[Digestive sys	stem]				
salivary gl	metastasis:peritoneum tumor	<32> 0	<43> 0	<38> 0	<28> 1
stomach	metastasis:peritoneum tumor	<32> 0	<43> 0	<38> 0	<28> 1
liver	leukemic cell infiltration	<32> 0	<43> 2	<38> 3	<28> 1
	metastasis:peritoneum tumor	0	0	0	1
(a) b	a: Number of animals examined at the sib: Number of animals with lesion	ite			

ANIMAL : RAT F344/DuCrj

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

PAGE: 2

SACRIFICED ANIMALS (105W)

Group Name 1000 ppm Control 2000 ppm 4000 ppm No. of Animals on Study 32 43 38 28 Findings_ [Digestive system] pancreas <32> <43> ⟨38⟩ <28> metastasis:peritoneum tumor [Urinary system] kidney <32> <43> <38> (28> leukemic cell infiltration [Reproductive system] testis <43> <38> ⟨28⟩ leukemic cell infiltration prostate <32> <43> ⟨38⟩ ⟨28⟩ leukemic cell infiltration [Body cavities] retroperit ⟨32⟩ ⟨43⟩ <38> ⟨28⟩ leukemic cell infiltration (a) a: Number of animals examined at the site b b: Number of animals with lesion (JPT150) BAIS3

APPENDIX N 4

HISTOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY, RAT: FEMALE: ALL ANIMALS (2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

b: Number of animals with lesion

REPORT TYPE : A1

SEX : FEMALE

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

Organ	Findings	Group Name Control No. of Animals on Study 50	1000 ppm 50	2000 ppm 50	4000 ppm 50
	•				
[Respiratory	system]				
nasal cavit	leukemic cell infiltration	<50> 0	<50> 0	<50> 0	<50>
trachea	metastasis:thyroid tumor	<50> 0	<50> 0	<50> 0	<50> 1
lung	leukemic cell infiltration	<50> 2	<50> 4	<50> 5	<50> 3
	metastasis:uterus tumor	• 0	0	0	1
	metastasis:thyroid tumor	0	0	0	1
	metastasis:bone tumor	0	0	1	0
[Hematopoieti	c system]				
one marrow	leukemic cell infiltration	<50> 1	<50> 3	<50> 5	<50> 8
	metastasis:liver tumor	0	0	1	0
ymph node	leukemic cell infiltration	<50> 0	<50> 1	<50> 2	<50> 1
	metastasis:uterus tumor	0	0	0	1
	metastasis:bone tumor	0	0	1	0
spleen	leukemic cell infiltration	<50> 0	<50> 1	<50> 1	<50> 0
	metastasis:liver tumor	0	0	1	0
[Circulatory	system]				
heart	leukemic cell infiltration	<50> 0	<50> 1	<50>	<50> 0

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 SEX : FEMALE

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

Organ	Findings	Group Name No. of Animals on Study	Control 50	1000 ppm 50	2000 ppm 50	4000 ppm 50
Digestive sy	stem]					
tomach	leukemic cell infiltration		<50> 0	<50> 1	<50> 2	<50> 0
nall intes	metastasis:uterus tumor		<50> 0	<50> 0	<50> 0	<50> 1
iver	leukemic cell infiltration		<50> 2	<50> 5	<50> 7	<50> 6
	metastasis:uterus tumor		0	0	0	1
ancreas	leukemic cell infiltration		<50> 0	<50> 2	<50> 1	<50> 0
Urinary syst	em]					
idney	leukemic cell infiltration		<50> 0	<50> 3	<50> 4	<50> 1
in bladd	leukemic cell infiltration		<50> 0	<50> 0	<50> 1	<50> 0
Endocrine sy	stem]					
ituitary	leukemic cell infiltration		<50> 0	<50> 0	<50> 5	<50>
nyroid	leukemic cell infiltration		<50> 0	<50> 0	<50> 1	<50> 0
drenal	leukemic cell infiltration		<50> 0	<50> 2	<50> 5	<50> 3
Reproductive	system]					
ovary	leukemic cell infiltration		<50> 0	<50> 0	<50> 3	<50> 0

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : FEMALE

Organ	Findings	Group Name No. of Animals on Study	Control 50	1000 ppm 50	2000 ppm 50	4000 ppm 50
[Reproductive	system]					
ovary	metastasis:uterus tumor		<50> 0	<50> 0	<50> 0	<50>
uterus	leukemic cell infiltration		<50> 0	<50> 1	<50> 1	<50> 0
vagina	leukemic cell infiltration		<50> 0	<50> 0	<50> 1	<50> 0
[Nervous syst	em]					
brain	leukemic cell infiltration		<50> 0	<50> 2	<50> 1	<50> 0
	metastasis:pituitary tumor		1	1	0	0
spinal cord	leukemic cell infiltration		<50> 0	<50> 0	<50> 2	<50> 0
[Special sens	e organs/appandage]					
еуе	leukemic cell infiltration		<50> 0	<50> 0	<50> 1	<50> 0
Harder gl	leukemic cell infiltration		<50> 0	<50> 0	<50> 1	<50> 1
[Body cavities	s]					
peritoneum	metastasis:uterus tumor		<50> 0	<50> 0	<50> 0	<50> 1
⟨a⟩ b	a: Number of animals examined at b: Number of animals with lesion	the site				
(JPT150)						BAIS

APPENDIX N 5

HISTOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY, RAT: FEMALE: DEAD AND MORIBUND ANIMALS (2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : FEMALE

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

Organ	Findings_	Group Name No. of Animals on Study	Cantrol 5	1000 ppm 10	2000 ppm 7	4000 ppm 20
[Respiratory	system]					
nasal cavit	leukemic cell infiltration		< 5> 0	<10> 0	< 7> 0	<20>
rachea	metastasis:thyroid tumor		< 5> 0	<10> 0	< 7> 0	<20>
ung	leukemic cell infiltration		< 5> 2	<10> 3	< 7>	<20>
	metastasis:uterus tumor		0	0	0	1
	metastasis:thyroid tumor		0	0	0	1
	metastasis:bone tumor		0	0	1	0
Hematopoiet	ic system]					
one marrow	leukemic coll infiltration		< 5> 0	<10> 2	< 7> 3	<20>
	metastasis:liver tumor		0	0	1	0
ymph node	leukemic cell infiltration		< 5> 0	<10> 0	< 7> 2	<20>
	metastasis:uterus tumor		0	0	0	1
	metastasis:bone tumor		0	0	1	0
spleen	leukemic cell infiltration		< 5> 0	<10>	< 7> 0	<20>
	metastasis:liver tumor		0	0	1	0
Circulatory	system]					
neart	leukemic cell infiltration		< 5> 0	<10> 1	< 7> 0	<20>

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

b

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

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE

PAGE: 6

Organ	Findings	Group Name Control No. of Animals on Study 5	1000 ppm 10	2000 ppm 7	4000 ppm 20
[Digestive s	ystem]				
stomach	leukemic cell infiltration	< 5> 0	<10> 1	< 7> 1	<20>
small intes	metastasis:uterus tumor	< 5> 0	<10> 0	< 7> 0	· <20>
liver	leukemic cell infiltration	< 5>	<10> 3	< 7> 4	<20> 4
	metastasis:uterus tumor	0	0	0	1
pancreas	leukemic cell infiltration	< 5> 0	<10> 2	< 7> 0	<20> 0
(Urinary sys	tem]				
kidney	leukemic cell infiltration	< 5> 0	<10> 3	< 7> 3	<20>
[Endocrine s	ystem]				
pituitary	leukemic cell infiltration	< 5> 0	<10> 0	< 7> 4	<20> 1
thyroid	leukemic cell infiltration	< 5> 0	<10> 0	< 7>	<20> 0
adrenal	leukemic cell infiltration	< 5> 0	<10> 1	< 7> 4	<20> 2
[Reproductiv	e system]				
ovary	leukemic cell infiltration	< 5> 0	<10> 0	< 7> 2	<20> 0
(a) b	a: Number of animals examined at the s b: Number of animals with lesion	ite			·
(JPT150)	W-W/15				BAISS

ANIMAL

: RAT F344/DuCrj

HISTOLOGICAL FINDINGS: METASTASIS OF TUMOR (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

REPORT TYPE : A1 : FEMALE

Group Name Control 1000 ppm 2000 ppm 4000 ppm No. of Animals on Study 10 20 Findings [Reproductive system] ovary < 5> <10> < 7> <20> metastasis:uterus tumor 0 0 uterus < 5> <10> < 7> <20> leukemic cell infiltration 0 [Nervous system] brain < 5> <10> < 7> (20> leukemic cell infiltration 0 2 1 0 metastasis:pituitary tumor 0 0 spinal cord < 5> <10> < 7> <20> leukemic cell infiltration 0 [Special sense organs/appandage] Harder gl < 5> <10> < 7> <20> leukemic cell infiltration [Rody cavities] peritoneum < 5> <10> < 7> <20> metastasis:uterus tumor 0 0 0 (a) a: Number of animals examined at the site b: Number of animals with lesion b (JPT150)

BAIS3

APPENDIX N 6

HISTOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY, RAT: FEMALE: SACRIFICED ANIMALS (2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

<a>>

b

a: Number of animals examined at the site

b: Number of animals with lesion

SEX : FEMALE

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

Organ	Findings	Group Name Control No. of Animals on Study 45'	1000 ppm 40	2000 ppm 43	4000 ppm 30.	
	- 1141155					
[Respiratory	system]					
lung	leukemic cell infiltration	<45> 0	<40> 1	<43> 1	<30> 0	
[Hematopoieti	c system]					
bone marrow	leukemic cell infiltration	<45>	<40> 1	<43> 2	<30> 3	
lymph node	leukemic cell infiltration	<45> 0	<40> 1	<43> 0	<30>	
spleen	leukemic cell infiltration	<45> 0	<40> 0	<43> 1	<30> 0	
[Circulatory	system]					
heart	leukemic cell infiltration	<45> 0	<40> 0	<43> 1	<30> 0	
[Digestive sy	stem]					
stomach	leukemic cell infiltration	<45> 0	<40> 0	<43> 1	<30> 0	
liver	leukemic cell infiltration	. <45>	<40> 2	<43> 3	<30> 2	
pancreas	leukemic cell infiltration	<45> 0	<40> 0	<43> 1	<30>	
[Urinary syst	em]					
kidney	leukemic cell infiltration	<45> 0	<40> 0	<43> 1	<30> 0	

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1
SEX : FEMA

(JPT150)

: FEMALE

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

PAGE: 4

BAIS3

0rgan	Findings	Group Name Control No. of Animals on Study 45	1000 ppm 40	2000 ppm 43	4000 ppm 30
[Urinary syst	tem]				
urin bladd	leukemic cell infiltration	<45> 0	<40> 0	<43> 1	<30> 0
(Endocrine sy	ystem]	•			
pituitary	leukemic cell infiltration	<45> 0	<40> 0	<43> 1	<30> 0
adrenal	leukemic cell infiltration	<45> 0	<40> 1	<43> 1	<30> 1
[Reproductive	ə system]				
DUATY	leukemic cell infiltration	<45> 0	<40> 0	<43> 1	<30> 0
uterus	leukemic cell infiltration	<45> 0	<40> 0	<43> 1	<30> 0
yagina	leukemic cell infiltration	<45> 0	<40> 0	<43> 1	<30> 0
(Nervous sys	tem]				
orain	metastasis:pituitary tumor	<45> 0	<40>	<43> 0	<30> 0
(Special sens	se organs/appandage]				
еуе	leukemic cell infiltration	<45> 0	<40> 0	<43> 1	<30> 0
⟨a⟩ b	a: Number of animals examined at the s b: Number of animals with lesion	ite			

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 : FEMALE SEX

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

Organ		Group Name No. of Animals on Study	Contral 45	. 1000 ppm 40	2000 ppm 43	4000 ppm 30
[Special ser	se organs/appandage]					
Harder gl	leukemic cell infiltration		<45> 0	<40> 0	<43> 1	<30> 0
(a) b	a : Number of animals examined at the s b : Number of animals with lesion	ite				

APPENDIX O1

IDENTITY OF DICHLOROMETHANE IN THE 2-YEAR INHALATION STUDY

IDENTITY OF DICHLOROMETHANE IN THE 2-YEAR INHALATION STUDY

Test Substance

: Dichloromethane (Wako Pure Chemical Industries, LTD.)

A. Lot No.

: APR5260

1. Spectral data

Mass Spectrometry

Instrument

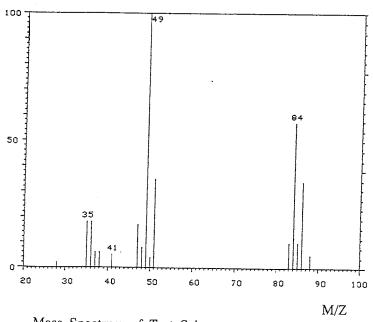
: Hitachi M-80B Mass Spectrometer

Ionization

: El (Electron Ionization)

Ionization Voltage

: 70eV



Mass Spectrum of Test Substance

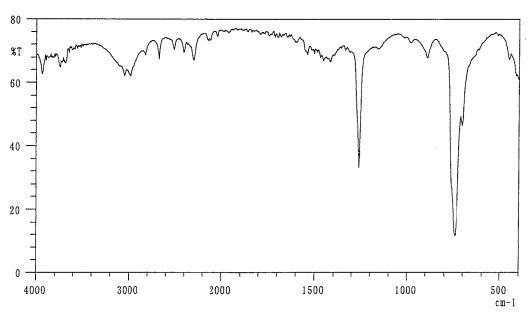
Results: The mass spectrum was consistent with literature spectrum.

<u>Determines</u>	<u>Literature Values</u> *
Fragment Peak (M/Z)	Fragment Peak (M/Z)
35	35
49	49
84	84
	(*EPA/NIH Mass Spectral Data Base (1978) Vol. 1, p. 33.)

Infrared Spectrometry

Instrument : Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell : KBr



Infrared Spectrum of Test Substance

Results: The infrared spectrum was consistent with literature spectrum.

Determined Values	Literature Values*
Wave Number (cm ⁻¹)	Wave Number (cm ⁻¹)
650~ 840	650~ 850
870~ 940	870~ 940
970~1000	970~1000
1120~1180	1130~1180
1200~1340	1200~1350
1370~1500	1380~1500
1530~1570	1540~1570
1580~1630	1580~1630
2040~2090	2050~2090
2100~2190	2120~2190
2250~2360	$2280\sim2370$
2380~2460	2400~2460
2500~2550	2500~2560
2650~2730	2650~2730
2800~2860	2800~2860
2900~3200	2900~3200
3650~3730	3670~3750
3730~3800	3750~3800
3900~4000	3900~4000
	(*Performed by the WAKO PURE
	CHEMICAL INDUSTRIES, LTD.)

2. Conclusions: The test substance was identified as dichloromethane, by the mass spectrum and the infrared spectrum.

B. Lot No.

: KCH4634

1. Spectral data

Mass Spectrometry

Instrument

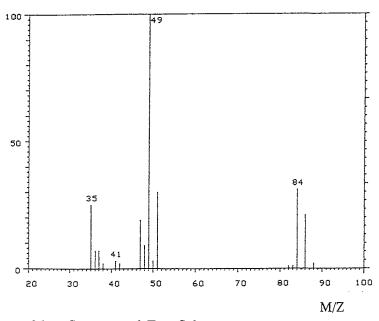
: Hitachi M-80B Mass Spectrometer

Ionization

: EI (Electron Ionization)

Ionization Voltage

: 70eV



Mass Spectrum of Test Substance

Determines

Results: The mass spectrum was consistent with literature spectrum.

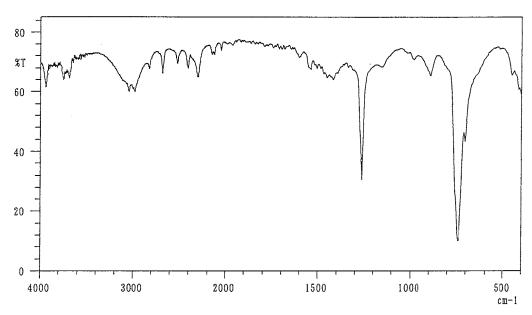
Fragment Peak (M/Z)	Fragment Peak (M/Z)
35	35
49	49
84	84
	(*EPA/NIH Mass Spectral Data Base (1978) Vol. 1, p. 33.)

Literature Values*

Infrared Spectrometry

Instrument : Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell : KBr



Infrared Spectrum of Test Substance

Results: The infrared spectrum was consistent with literature spectrum.

Determined Values	Literature Values*
Wave Number (cm ⁻¹)	Wave Number (cm ⁻¹)
650~ 840	650~ 850
870~ 940	870~ 940
970~1000	970~1000
1120~1180	1130~1180
1200~1340	1200~1350
1370~1500	1380~1500
1530~1570	1540~1570
1580~1630	1580~1630
2040~2090	2050~2090
2100~2190	2120~2190
2250~2360	2280~2370
2380~2460	2400~2460
2500~2550	2500~2560
2650~2730	2650~2730
2800~2860	2800~2860
2900~3200	2900~3200
3650~3730	3670~3750
3730~3800	3750~3800
3900~4000	3900~4000
	(*Performed by the WAKO PURE
	CHEMICAL INDUSTRIES, LTD.)

2. Conclusions: The test substance was identified as dichloromethane, by the mass spectrum and the infrared spectrum.

C. Lot No.

: ESR7256

1. Spectral data

Mass Spectrometry

Instrument

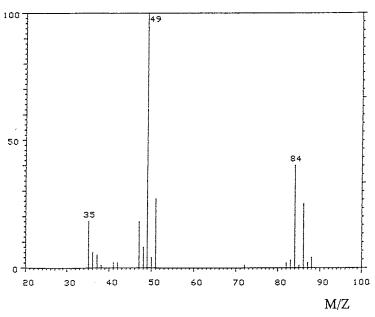
: Hitachi M-80B Mass Spectrometer

Ionization

: EI (Electron Ionization)

Ionization Voltage

: 70eV



Mass Spectrum of Test Substance

Results: The mass spectrum was consistent with literature spectrum.

<u>Determines</u>	Literature Values*
Fragment Peak (M/Z)	Fragment Peak (M/Z)
35	35
49	49
84	84
	(*EPA/NIH Mass Spectral
	Data Base (1978) Vol. 1, p. 33.)

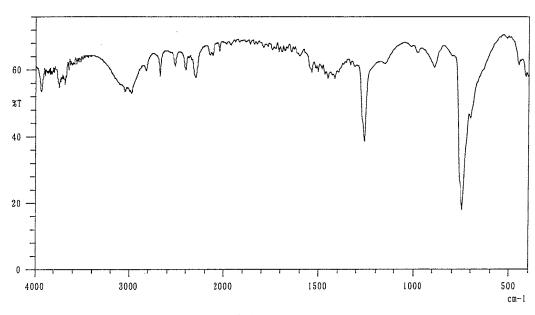
Infrared Spectrometry

Instrument

: Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell

: KBr



Infrared Spectrum of Test Substance

Results: The infrared spectrum was consistent with literature spectrum.

Determined Values	Literature Values*
Wave Number (cm ⁻¹)	Wave Number(cm ⁻¹)
650~ 840	650~ 850 ` ´
870~ 940	870~ 940
970~1000	970~1000
1120~1180	1130~1180
1200~1340	1200~1350
1370~1500	1380~1500
1530~1570	1540~1570
1580~1630	1580~1630
2040~2090	2050~2090
2100~2190	2120~2190
2250~2360	2280~2370
2380~2460	2400~2460
2500~2550	2500~2560
2650~2730	2650~2730
2800~2860	2800~2860
2900~3200	2900~3200
3650~3730	3670~3750
3730~3800	3750~3800
3900~4000	3900~4000
	(*Performed by the WAKO PURE
	CHEMICAL INDUSTRIES, LTD.)

2. Conclusions: The test substance was identified as dichloromethane, by the mass spectrum and the infrared spectrum.

D. Lot No.

: ESM2924

1. Spectral data

Mass Spectrometry

Instrument

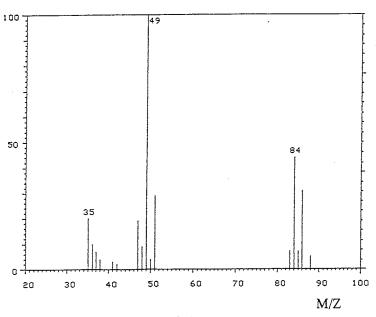
: Hitachi M-80B Mass Spectrometer

Ionization

: EI (Electron Ionization)

Ionization Voltage

: 70eV



Mass Spectrum of Test Substance

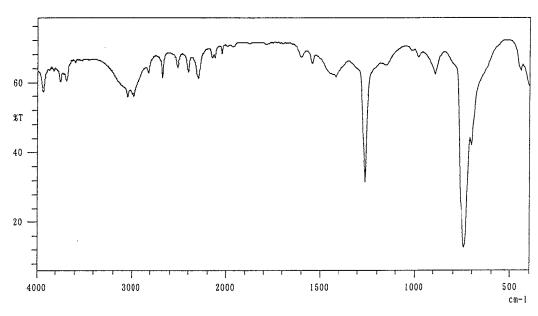
Results: The mass spectrum was consistent with literature spectrum.

Determines	Literature Values
Fragment Peak (M/Z)	Fragment Peak (M/Z)
35	35
49	49
84	84
	*EPA/NIH Mass Spectral
	Data Base (1978) Vol. 1, p. 33.)

Infrared Spectrometry

Instrument : Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell : KBr



Infrared Spectrum of Test Substance

Results: The infrared spectrum was consistent with literature spectrum.

	*
Determined Values	<u>Literature Values</u>
Wave Number (cm ⁻¹)	Wave Number (cm ⁻¹)
650~ 840	650~ 850
870~ 940	870~ 940
970~1000	970~1000
	1130~1180
1120~1180	
1200~1340	1200~1350
$1370 \sim 1500$	1380~1500
1530~1570	1540~1570
1580~1630	1580~1630
2040~2090	2050~2090
2100~2190	2120~2190
2250~2360	2280~2370
2380~2460	2400~2460
2500~2550	2500~2560
2650~2730	2650~2730
2800~2860	2800~2860
2900~3200 2900~3200	2900~3200
	3670~3750
3650~3730	
3730~3800	3750~3800
3900~4000	3900~4000
	(*Performed by the WAKO PURE
	CHEMICAL INDUSTRIES, LTD.)

2. Conclusions: The test substance was identified as dichloromethane, by the mass spectrum and the infrared spectrum.

E. Lot No.

: ESJ4826

1. Spectral data

Mass Spectrometry

Instrument

: Hitachi M-80B Mass Spectrometer

Ionization

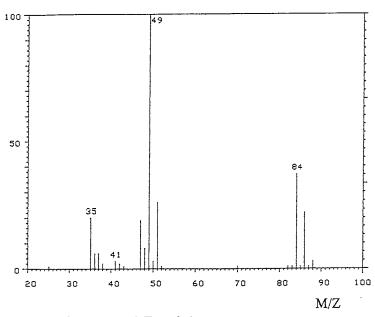
)

)

: EI (Electron Ionization)

Ionization Voltage

: 70eV



Mass Spectrum of Test Substance

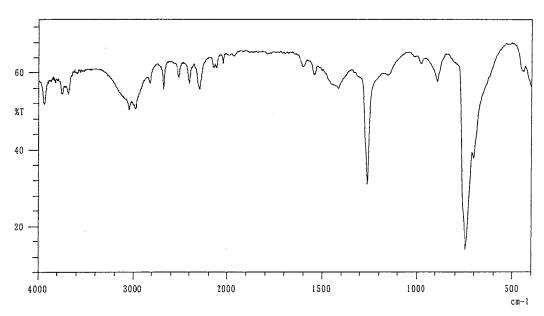
Results: The mass spectrum was consistent with literature spectrum.

<u>Determines</u>	<u>Literature Values</u>
Fragment Peak (M/Z)	Fragment Peak (M/Z)
35	35
49	49
84	84
	(*EPA/NIH Mass Spectral
	Data Base (1978) Vol. 1, p. 33.)

Infrared Spectrometry

Instrument : Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell : KBr



Infrared Spectrum of Test Substance

Results: The infrared spectrum was consistent with literature spectrum.

Determined Values Wave Number (cm ⁻¹) 650~ 840 870~ 940 970~1000 1120~1180 1200~1340 1370~1500 1530~1570 1580~1630 2040~2090 2100~2190	Literature Values Wave Number (cm ⁻¹) 650~ 850 870~ 940 970~1000 1130~1180 1200~1350 1380~1500 1540~1570 1580~1630 2050~2090 2120~2190
2250~2360 2380~2460 2500~2550 2650~2730 2800~2860 2900~3200 3650~3730 3730~3800 3900~4000	2280~2370 2400~2460 2500~2560 2650~2730 2800~2860 2900~3200 3670~3750 3750~3800 3900~4000 (*Performed by the WAKO PURE CHEMICAL INDUSTRIES, LTD.)

2. Conclusions: The test substance was identified as dichloromethane, by the mass spectrum and the infrared spectrum.

F. Lot No.

: ESF6669

1. Spectral data

Mass Spectrometry

Instrument

: Hitachi M-80B Mass Spectrometer

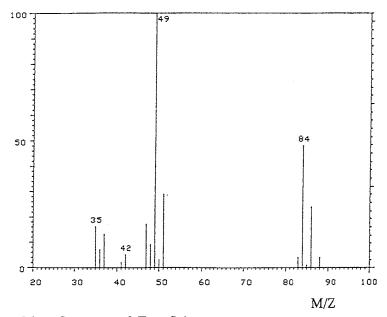
Ionization

)

: EI (Electron Ionization)

Ionization Voltage

: 70eV



Mass Spectrum of Test Substance

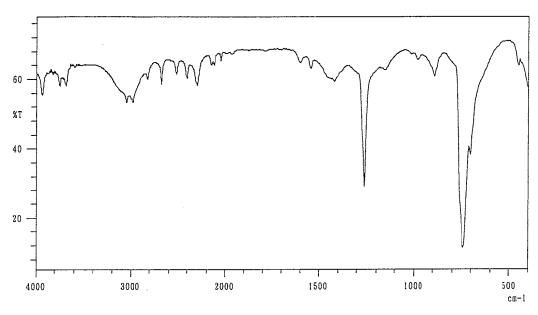
Results: The mass spectrum was consistent with literature spectrum.

<u>Determines</u> Fragment Peak (M/Z)	<u>Literature Values*</u> Fragment Peak (M/Z)
35	35
49	49
84	84
	(*EPA/NIH Mass Spectral
	Data Base (1978) Vol. 1, p. 33.)

Infrared Spectrometry

Instrument : Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell : KBr



Infrared Spectrum of Test Substance

Results: The infrared spectrum was consistent with literature spectrum.

Determined Values Wave Number (cm ⁻¹) 650~ 840 870~ 940 970~1000 1120~1180 1200~1340 1370~1500 1530~1570 1580~1630 2040~2090 2100~2190 2250~2360	Literature Values* Wave Number (cm ⁻¹) 650~ 850 870~ 940 970~1000 1130~1180 1200~1350 1380~1500 1540~1570 1580~1630 2050~2090 2120~2190 2280~2370
-200 -270	
2380~2460 2500~2550 2650~2730	$2400 \sim 2460$ $2500 \sim 2560$ $2650 \sim 2730$
2800~2860 2900~3200	2800~2860 2900~3200
3650~3730 3730~3800 3900~4000	3670∼3750 3750∼3800 3900∼4000
3700 4000	(*Performed by the WAKO PURE CHEMICAL INDUSTRIES, LTD.)

2. Conclusions: The test substance was identified as dichloromethane, by the mass spectrum and the infrared spectrum.

G. Lot No.

: DLP1873

1. Spectral data

Mass Spectrometry

Instrument

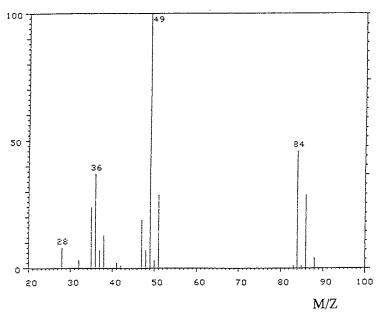
: Hitachi M-80B Mass Spectrometer

Ionization

: EI (Electron Ionization)

Ionization Voltage

: 70eV



Mass Spectrum of Test Substance

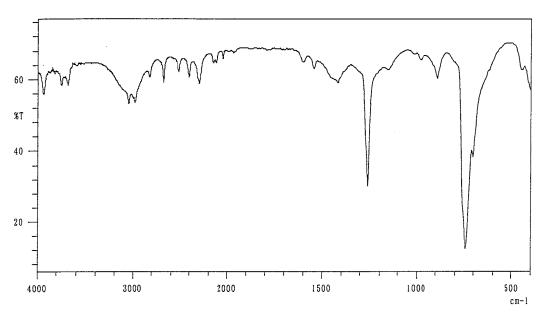
Results: The mass spectrum was consistent with literature spectrum.

<u>Determines</u>	Literature Values
Fragment Peak (M/Z)	Fragment Peak (M/Z)
35	35
49	49
84	84
	(*EPA/NIH Mass Spectral
	Data Base (1978) Vol. 1, p. 33.)

Infrared Spectrometry

Instrument : Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell : KBr



Infrared Spectrum of Test Substance

Results: The infrared spectrum was consistent with literature spectrum.

Determined Values Wave Number (cm ⁻¹) 650~ 840 870~ 940	Literature Values* Wave Number (cm ⁻¹) 650~ 850 870~ 940
970~1000 1120~1180	970~1000 1130~1180
1200~1340	1200~1350
1370~1500	1380~1500
1530~1570	1540~1570 1580~1630
1580~1630 2040~2090	2050~2090
2100~2190	2120~2190
2250~2360	2280~2370
2380~2460	2400~2460 2500~2560
2500~2550 2650~2730	2650~2730 2650~2730
2800~2860	2800~2860
2900~3200	2900~3200
3650~3730	3670~3750 3750~ 3800
3730~3800 3900~4000	3750~3800 3900~4000
3700 1000	(*Performed by the WAKO PURE
	CHEMICAL INDUSTRIES, LTD.)

2. Conclusions: The test substance was identified as dichloromethane, by the mass spectrum and the infrared spectrum.

H. Lot No.

: DLL3810

1. Spectral data

Mass Spectrometry

Instrument

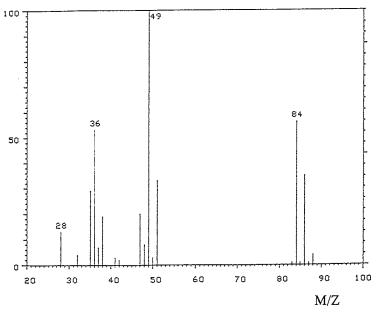
: Hitachi M-80B Mass Spectrometer

Ionization

: EI (Electron Ionization)

Ionization Voltage

: 70eV



Mass Spectrum of Test Substance

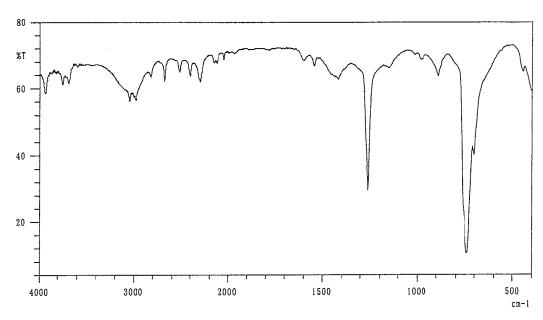
Results: The mass spectrum was consistent with literature spectrum.

<u>Determines</u> Fragment Peak (M/Z)	<u>Literature Values*</u> Fragment Peak (M/Z)
35	35
49	49
84	84
	(*EPA/NIH Mass Spectral Data Base (1978) Vol. 1, p. 33.)

Infrared Spectrometry

Instrument : Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell : KBr



Infrared Spectrum of Test Substance

Results: The infrared spectrum was consistent with literature spectrum.

Determined Values	Literature Values*
Wave Number (cm ⁻¹)	Wave Number (cm ⁻¹)
650~ 840	650~ 850
870~ 940	870~ 940
970~1000	970~1000
$1120 \sim 1180$	1130~1180
1200~1340	1200~1350
1370~1500	1380~1500
1530~1570	1540~1570
1580~1630	1580~1630
2040~2090	2050~2090
2100~2190	2120~2190
2250~2360	2280~2370
2380~2460	2400~2460
2500~2550	2500~2560
2650~2730	2650~2730
2800~2860	2800~2860
2900~3200	2900~3200
3650~3730	3670~3750
3730~3800	3750~3800
3900~4000	3900~4000
	(*Performed by the WAKO PURE
	CHEMICAL INDUSTRIES, LTD.)

2. Conclusions: The test substance was identified as dichloromethane, by the mass spectrum and the infrared spectrum.

I. Lot No.

: DLH5609

1. Spectral data

Mass Spectrometry

Instrument

: Hitachi M-80B Mass Spectrometer

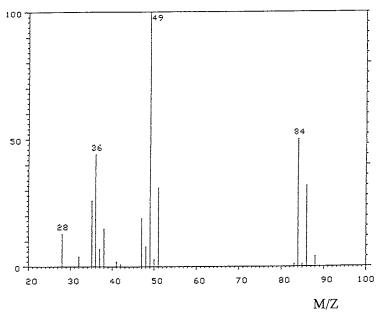
Ionization

)

: EI (Electron Ionization)

Ionization Voltage

: 70eV



Mass Spectrum of Test Substance

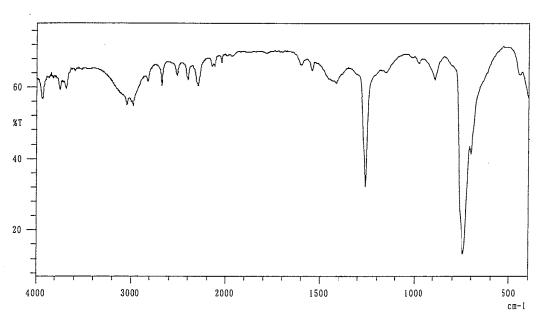
Results: The mass spectrum was consistent with literature spectrum.

Determines Fragment Peak (M/Z)	<u>Literature Values*</u> Fragment Peak (M/Z)
35	35
49	49
84	84
	(*EPA/NIH Mass Spectral Data Base (1978) Vol. 1, p. 33.)

Infrared Spectrometry

Instrument : Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell : KBr



Infrared Spectrum of Test Substance

Results: The infrared spectrum was consistent with literature spectrum.

	*
Determined Values	<u>Literature Values</u>
Wave Number (cm ⁻¹)	Wave Number (cm ⁻¹)
650~ 840	650~ 850
870~ 940	870~ 940
970~1000	970~1000
1120~1180	1130~1180
1200~1340	1200~1350
1370~1500	1380~1500
1530~1570	1540~1570
1580~1630	1580~1630
2040~2090	2050~2090
2100~2190	2120~2190
2250~2360	2280~2370
2380~2460	2400~2460
2500~2550	2500~2560
2650~2730	2650~2730
2800~2860	2800~2860
2900~3200	2900~3200
3650~3730	3670~3750
3730~3800	3750~3800
3900~4000	3900~4000
	(*Performed by the WAKO PURE
	CHEMICAL INDUSTRIES, LTD.)
	CHEMICAL INDUSTRIES, LID.)

2. Conclusions: The test substance was identified as dichloromethane, by the mass spectrum and the infrared spectrum.

APPENDIX O 2 STABILITY OF DICHLOROMETHANE IN THE 2-YEAR INHALATION STUDY

STABILITY OF DICHLOROMETHANE IN THE 2-YEAR INHALATION STUDY

Test Substance : Dichloromethane (Wako Pure Chemical Industries, LTD.)

A. Lot No. : APR5260

1. Sample : This lot was used from 1994.10.20 to 1995.1.9. Test substance was stored at room

temperature.

2.Infrared Spectrometry

Instrument : Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell : KBr

Results: The result of infrared spectrum did not change when before and after studies.

1995.01.09 (date analyzed)
Wave Number (cm ⁻¹)
650~ 840
870~ 940
970~1000
1120~1180
1200~1340
1370~1500
1530~1570
1580~1630
2040~2090
2100~2190
2250~2360
2380~2460
2500~2550
2650~2730
2800~2860
2900~3200
3650~3730
3730~3800
3900~4000

3. Gas Chromatography

)

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : Methyl Silicone $(0.2 \text{mm } \phi \times 50 \text{m})$

Column Temperature : 60° C

Flow Rate : 1 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μL

Results: Gas chromatography indicated one major peak (peak No.1) and one impurity (peak No.2 < 1% of total area) analyzed at 1994.10.7 and one major peak (peak No.1) and one impurity (peak No.2 < 1% of total area) analyzed at 1995.1.9. It was identified only by comparing its gas chromatograph with that of the amylene (peak No.2) in the dichloromethane, the amount in the test substance were 0.0008% at 1994.10.7. No new trace impurity peak in the test substance analyzed at 1995.1.9 was detected.

Date	Peak No.	Retention Time (min)	Area (%)	
1994.10.07	1	3.302	99.99	
	2	3.403	0.01	
1995.01.09	1	3.305	99.99	
	2	3.407	0.01	

^{4.} Conclusions: The test substance was stable for about 3 months in the dark at room temperature.

B. Lot No.

: KCH4634

1.Sample

: This lot was used from 1995.1.7 to 1995.4.3. Test substance was stored at room

temperature.

2.Infrared Spectrometry

Instrument : Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell : KBr

Slit

)

: Medium

1994.12.27 (date analyzed)	1995.04.03 (date analyzed)
Wave Number (cm ⁻¹)	Wave Number (cm ⁻¹)
650~ 840 `	650~ 840
870~ 940	870~ 940
970~1000	970~1000
1120~1180	1120~1180
1200~1340	1200~1340
1370~1500	1370~1500
1530~1570	1530~1570
1580~1630	1580~1630
2040~2090	2040~2090
2100~2190	2100~2190
2250~2360	2250~2360
2380~2460	2380~2460
2500~2550	2500~2550
2650~2730	2650~2730
2800~2860	2800~2860
2900~3200	2900~3200
3650~3730	3650~3730
3730~3800	3730~3800
3900~4000	3900~4000

3. Gas Chromatography

Instrument

: Hewlett Packard 5890A Gas Chromatograph

Column

: Methyl Silicone (0.2mm $\phi \times 50$ m)

Column Temperature : 60° C

Flow Rate

: 1 mL/min

Detector

: FID (Flame Ionization Detector)

Injection Volume

: 1 µL

Results: Gas chromatography indicated one major peak (peak No.1) and one impurity (peak No.2 < 1% of total area) analyzed at 1994.12.27 and one major peak (peak No.1) and one impurity (peak No.2 < 1% of total area) analyzed at 1995.4.3. It was identified only by comparing its gas chromatograph with that of the amylene (peak No.2) in the dichloromethane, the amount in the test substance were 0.0008% at 1995.4.3. No new trace impurity peak in the test substance analyzed at 1995.1.9 was detected.

Date	Peak No.	Retention Time (min)	Area (%)	
1994.12.27	1	3.3	99.98	
	2	3.407	0.02	
1995.04.03	1	3.307	99.99	
	2	3.407	0.01	

^{4.} Conclusions: The test substance was stable for about 3 months in the dark at room temperature.

C. Lot No.

: ESR7256

1.Sample

: This lot was used from 1995.4.4 to 1995.6.28. Test substance was stored at room

temperature.

2.Infrared Spectrometry

Instrument

: Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell

)

: KBr

Results: The result of infrared spectrum did not change when before and after studies.

1995.03.27 (date analyzed)	1995.06.28 (date analyzed)
Wave Number(cm ⁻¹)	Wave Number (cm ⁻¹)
650~ 840	650~ 840
870~ 940	870~ 940
970~1000	970~1000
1120~1180	1120~1180
1200~1340	1200~1340
1370~1500	1370~1500
1530~1570	1530~1570
1580~1630	1580~1630
2040~2090	2040~2090
2100~2190	2100~2190
2250~2360	2250~2360
2380~2460	2380~2460
2500~2550	2500~2550
2650~2730	2650~2730
2800~2860	2800~2860
2900~3200	2900~3200
3650~3730	3650~3730
3730~3800	3730~3800
3900~4000	3900~4000

3. Gas Chromatography

Instrument

: Hewlett Packard 5890A Gas Chromatograph

Column

: Methyl Silicone (0.2mm $\phi \times 50$ m)

Column Temperature : 60° C

Flow Rate

: 1 mL/min

Detector

: FID (Flame Ionization Detector)

Injection Volume

: 1 µL

Results: Gas chromatography indicated one major peak (peak No.1) and one impurity (peak No.2 < 1% of total area) analyzed at 1995.3.27 and one major peak (peak No.1) and one impurity (peak No.2 < 1% of total area) analyzed at 1995.6.28. It was identified only by comparing its gas chromatograph with that of the amylene (peak No.2) in the dichloromethane, the amount in the test substance were 0.0008% at 1995.3.27. No new trace impurity peak in the test substance analyzed at 1995.6.28 was detected.

Date	Peak No.	Retention Time (min)	Area (%)	
1995.03.27	1	3.302	99.98	
	2	3.407	0.02	
1995.06.28	1	3.302	99.81	
	2	3.405	0.19	

^{4.} Conclusions: The test substance was stable for about 3 months in the dark at room temperature.

D. Lot No.

: ESM2924

1.Sample

: This lot was used from 1995.6.28 to 1995.9.22. Test substance was stored at room

temperature.

2.Infrared Spectrometry

Instrument

: Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell

)

: KBr

Results: The result of infrared spectrum did not change when before and after studies.

1995.06.26 (date analyzed)	1995.10.02 (date analyzed)
Wave Number (cm ⁻¹)	Wave Number (cm ⁻¹)
650~ 840	650~ 840
870~ 940	870~ 940
970~1000	970~1000
1120~1180	1120~1180
1200~1340	1200~1340
1370~1500	1370~1500
1530~1570	1530~1570
1580~1630	1580~1630
2040~2090	2040~2090
2100~2190	2100~2190
2250~2360	2250~2360
2380~2460	2380~2460
2500~2550	2500~2550
2650~2730	2650~2730
2800~2860	2800~2860
2900~3200	2900~3200
3650~3730	3650~3730
3730~3800	3730~3800
3900~4000	3900~4000

3. Gas Chromatography

Instrument

: Hewlett Packard 5890A Gas Chromatograph

Column

: Methyl Silicone (0.2mm $\phi \times 50$ m)

Column Temperature

: 60° C

Flow Rate

: 1 mL/min

Detector

: FID (Flame Ionization Detector)

Injection Volume

: 1 μL

Results: Gas chromatography indicated one major peak (peak No.1) and one impurity (peak No.2 < 1% of total area) analyzed at 1995.6.26 and one major peak (peak No.1) and one impurity (peak No.2 < 1% of total area) analyzed at 1995.10.2. It was identified only by comparing its gas chromatograph with that of the amylene (peak No.2) in the dichloromethane, the amount in the test substance were 0.0008% at 1995.6.26. No new trace impurity peak in the test substance analyzed at 1995.10.2 was detected.

Date	Peak No.	Retention Time (min)	Area (%)	
1995.06.26	1	3.302	99.99	
	2	3.405	0.01	
1995.10.02	1	3.302	99.99	
	2	3.405	0.01	

^{4.} Conclusions: The test substance was stable for about 4 months in the dark at room temperature.

E. Lot No.

: ESJ4826

1.Sample

: This lot was used from 1995.9.22 to 1995.12.25. Test substance was stored at

room temperature.

2.Infrared Spectrometry

Instrument

: Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell

)

: KBr

Results: The result of infrared spectrum did not change when before and after studies.

1995.09.14 (date analyzed)	1995.12.25 (date analyzed)
Wave Number (cm ⁻¹)	Wave Number (cm ⁻¹)
650~ 840	650~ 840
870~ 940	870~ 940
970~1000	970~1000
1120~1180	1120~1180
1200~1340	1200~1340
1370~1500	1370~1500
1530~1570	1530~1570
1580~1630	1580~1630
2040~2090	2040~2090
2100~2190	2100~2190
2250~2360	2250~2360
2380~2460	2380~2460
2500~2550	2500~2550
2650~2730	2650~2730
2800~2860	2800~2860
2900~3200	2900~3200
3650~3730	3650~3730
3730~3800	3730~3800
3900~4000	3900~4000

3. Gas Chromatography

Instrument

: Hewlett Packard 5890A Gas Chromatograph

Column

: Methyl Silicone (0.2mm $\phi \times 50$ m)

Column Temperature : 60° C

Flow Rate

: 1 mL/min

Detector

: FID (Flame Ionization Detector)

Injection Volume

: 1 µL

Results: Gas chromatography indicated one major peak (peak No.2) and one impurity (peak No.2 and peak No.2 < 1% of total area) analyzed at 1995.9.14 and one major peak (peak No.1) and one impurity (peak No.2 < 1% of total area) analyzed at 1995.12.25. It was identified only by comparing its gas chromatograph with that of the amylene (peak No.3) in the dichloromethane, the amount in the test substance were 0.0004% at 1995.9.14. No new trace impurity peak in the test substance analyzed at 1995.12.25 was detected.

Date	Peak No.	Retention Time (min)	Area (%)	
1995.09.14	1	3.27	0.001	
	2	3.305	99.987	
	3	3.408	0.012	
1995.12.25	1	3.302	99.99	
	2	3.407	0.01	

^{4.} Conclusions: The test substance was stable for about 3 months in the dark at room temperature.

F. Lot No.

: ESF6669

1.Sample

: This lot was used from 1995.12.25 to 1996.4.1. Test substance was stored at room

temperature.

2.Infrared Spectrometry

Instrument

: Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell

)

: KBr

Results: The result of infrared spectrum did not change when before and after studies.

1995.12.22 (date analyzed)	1996.04.02 (date analyzed)
Wave Number (cm ⁻¹)	Wave Number (cm ⁻¹)
650~ 840 `	650~ 840 `
870~ 940	870~ 940
970~1000	970~1000
1120~1180	1120~1180
1200~1340	1200~1340
1370~1500	1370~1500
1530~1570	1530~1570
1580~1630	1580~1630
2040~2090	2040~2090
2100~2190	2100~2190
2250~2360	2250~2360
2380~2460	2380~2460
2500~2550	2500~2550
2650~2730	2650~2730
2800~2860	2800~2860
2900~3200	2900~3200
3650~3730	3650~3730
3730~3800	3730~3800
3900~4000	3900~4000

3. Gas Chromatography

Instrument

: Hewlett Packard 5890A Gas Chromatograph

Column

: Methyl Silicone (0.2mm $\phi \times 50$ m)

Column Temperature : 60° C

Flow Rate

: 1 mL/min

Detector

: FID (Flame Ionization Detector)

Injection Volume

: 1 μL

Results: Gas chromatography indicated one major peak (peak No.1) and one impurity (peak No.2 < 1% of total area) analyzed at 1995.12.22 and one major peak (peak No.1) and one impurity (peak No.2 < 1% of total area) analyzed at 1996.4.2. It was identified only by comparing its gas chromatograph with that of the amylene (peak No.2) in the dichloromethane, the amount in the test substance were 0.0007 % at 1995.12.22. No new trace impurity peak in the test substance analyzed at 1996.4.2 was detected.

Date	Peak No.	Retention Time (min)	Area (%)	
1995.12.22	1	3.302	99.83	
	2	3.405	0.17	
1996.04.02	1	3.302	99.99	
	2	3.405	0.01	

^{4.} Conclusions: The test substance was stable for about 4 months in the dark at room temperature.

G. Lot No.

: DLP1873

1.Sample

: This lot was used from 1996.4.1 to 1996.6.27. Test substance was stored at room

temperature.

2.Infrared Spectrometry

Instrument

: Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell

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: KBr

Results: The result of infrared spectrum did not change when before and after studies.

1996.03.25 (date analyzed)	1996.06.28 (date analyzed)
Wave Number (cm ⁻¹)	Wave Number (cm ⁻¹)
650~ 840	650~ 840
870~ 940	870~ 940
970~1000	970~1000
1120~1180	1120~1180
1200~1340	1200~1340
1370~1500	1370~1500
1530~1570	1530~1570
1580~1630	1580~1630
2040~2090	2040~2090
2100~2190	2100~2190
2250~2360	2250~2360
2380~2460	2380~2460
2500~2550	2500~2550
2650~2730	2650~2730
2800~2860	2800~2860
2900~3200	2900~3200
3650~3730	3650~3730
3730~3800	3730~3800
3900~4000	3900~4000

3. Gas Chromatography

Instrument

: Hewlett Packard 5890A Gas Chromatograph

Column

: Methyl Silicone(0.2mm $\phi \times 50$ m)

Column Temperature : 60° C

Flow Rate

: 1 mL/min

Detector

: FID (Flame Ionization Detector)

Injection Volume

: 1 µL

Results: Gas chromatography indicated one major peak (peak No.1) and one impurity (peak No.2 < 1% of total area) analyzed at 1996.3.25 and one major peak (peak No.1) and one impurity (peak No.2 < 1% of total area) analyzed at 1996.6.28. It was identified only by comparing its gas chromatograph with that of the amylene (peak No.2) in the dichloromethane, the amount in the test substance were 0.0006% at 1996.3.25. No new trace impurity peak in the test substance analyzed at 1996.6.28 was detected.

Date	Peak No.	Retention Time (min)	Area (%)	
1996.03.25	1	3.302	99.98	
	2	3.407	0.02	
1996.06.28	1	3.302	99.98	
	2	3.407	0.02	

^{4.} Conclusions: The test substance was stable for about 3 months in the dark at room temperature.

H. Lot No.

: DLL3810

1.Sample

: This lot was used from 1996.6.28 to 1996.9.26. Test substance was stored at room

temperature.

2.Infrared Spectrometry

Instrument

: Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell

: KBr

Results: The result of infrared spectrum did not change when before and after studies.

1996.06.26 (date analyzed)	1996.09.26 (date analyzed)
Wave Number (cm ⁻¹)	Wave Number (cm ⁻¹)
650~ 840 `	650~ 840
870~ 940	870~ 940
970~1000	970~1000
1120~1180	1120~1180
1200~1340	1200~1340
1370~1500	1370~1500
1530~1570	1530~1570
1580~1630	1580~1630
2040~2090	2040~2090
2100~2190	2100~2190
2250~2360	2250~2360
2380~2460	2380~2460
2500~2550	2500~2550
2650~2730	2650~2730
2800~2860	2800~2860
2900~3200	2900~3200
3650~3730	3650~3730
3730~3800	3730~3800
3900~4000	3900~4000

3. Gas Chromatography

Instrument

: Hewlett Packard 5890A Gas Chromatograph

Column

: Methyl Silicone $(0.2 \text{mm} \, \phi \times 50 \text{m})$

Column Temperature

: 60°C

Flow Rate

: 1 mL/min

Detector

: FID (Flame Ionization Detector)

Injection Volume

: 1 µL

Results: Gas chromatography indicated one major peak (peak No.1) and one impurity (peak No.2 < 1% of total area) analyzed at 1996.6.26 and one major peak (peak No.1) and one impurity(peak No.2 < 1% of total area) analyzed at 1996.9.26. It was identified only by comparing its gas chromatograph with that of the amylene (peak No.2) in the dichloromethane, the amount in the test substance were 0.0007% at 1996.6.26. No new trace impurity peak in the test substance analyzed at 1996.9.26 was detected.

Date	Peak No.	Retention Time (min)	Area (%)	
1996.06.26	1	3.302	99.98	
	2	3.407	0.02	
1996.09.26	1	3.302	99.99	
	2	3.407	0.01	

^{4.} Conclusions: The test substance was stable for about 3 months in the dark at room temperature.

I. Lot No. : DLH5609

1.Sample

: This lot was used from 1996.9.27 to 1996.10.16. Test substance was stored at roo

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temperature.

2.Infrared Spectrometry

Instrument

: Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell

: KBr

Results: The result of infrared spectrum did not change when before and after studies.

10060007 (1)	1006 11 05 (1 / 1 / 1 / 1)
1996.09.25 (date analyzed)	1996.11.25 (date analyzed)
Wave Number (cm ⁻¹)	Wave Number (cm ⁻¹)
650~ 840	650~ 840
870~ 940	870~ 940
970~1000	970~1000
1120~1180	1120~1180
1200~1340	1200~1340
1370~1500	1370~1500
1530~1570	1530~1570
1580~1630	1580~1630
2040~2090	2040~2090
2100~2190	2100~2190
2250~2360	2250~2360
2380~2460	2380~2460
2500~2550	2500~2550
2650~2730	2650~2730
2800~2860	2800~2860
2900~3200	2900~3200
3650~3730	3650~3730
3730~3800	3730~3800
3900~4000	3900~4000

3. Gas Chromatography

Instrument

: Hewlett Packard 5890A Gas Chromatograph

Column

: Methyl Silicone(0.2mm $\phi \times 50$ m)

Column Temperature : 60° C

Flow Rate

: 1 mL/min

Detector

: FID (Flame Ionization Detector)

Injection Volume

: 1 μL

Results: Gas chromatography indicated one major peak (peak No.1) and one impurity (peak No.2 < 1% of total area) analyzed at 1996.9.25 and one major peak (peak No.1) and one impurity (peak No.2 < 1% of total area) analyzed at 1996.11.25. It was identified only by comparing its gas chromatograph with that of the amylene (peak No.2) in the dichloromethane, the amount in the test substance were 0.0008% at 1996.9.25. No new trace impurity peak in the test substance analyzed at 1996.11.25 was detected.

Date	Peak No.	Retention Time (min)	Area (%)	
1996.09.25	1	3.302	99.99	
	2	3.407	0.01	
1996.11.25	1	3.303	99.98	
	2	3.407	0.02	

^{4.} Conclusions: The test substance was stable for about 3 months in the dark at room temperature.

APPENDIX P1

CONCENTRATION OF DICHLOROMETHANE IN THE INHALATION CHAMBER OF THE 2-YEAR INHALATION STUDY

CONCENTRATION OF DICHLROMETHANE IN THE INHALATION CHAMBER OF THE 2-YEAR INHALATION STUDY

Group Name	Concentration (ppm) Mean ± S.D.
Control	0.0 ± 0.0
1000ppm	999.9 ± 6.5
2000ppm	2003.2 ± 9.0
4000ppm	3988.5 ± 25.7

APPENDIX P2

ENVIRONMETAL CONDITIONS OF INHALATION CHAMBER IN THE 2-YEAR INHALATION STUDY OF DICHLOROMETHANE

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 2-YEAR INHALATION STUDY OF DICHLOROMETHANE

Group Name	Temperature(°C) Mean \pm S.D.	Humidity(%) Mean ± S.D.	Ventilation Rate(L/min) Mean ± S.D.	Air Changes(time/h) Mean
Control	22.4 ± 0.2	54.8 ± 1.4	$1831.0 \pm 9.2 \ (916.4 \pm 3.3)$	12.1 (6.0)
1000ppm	22.2 ± 0.2	54.5 ± 1.5	$1825.4 \pm 8.9 \ (917.9 \pm 2.8)$	12.0 (6.0)
2000ppm	22.2 ± 0.1	55.6 ± 1.4	$1826.0 \pm 8.6 \ (915.9 \pm 2.3)$	12.0 (6.0)
4000ppm	22.2 ± 0.1	55.0 ± 1.6	$1830.1 \pm 8.2 \ (916.1 \pm 2.5)$	12.1 (6.0)

():during exposure

APPENDIX Q1

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS IN THE 2-YEAR INHALATION STUDY OF DICHLOROMERHANE

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS IN THE 2-YEAR INHALATION STUDY OF DICHLOROMETHANE

Item	Method
Hematology	
Red blood cell (RBC)	Light scattering method 1)
Hemoglobin (Hgb)	Cyanmethemoglobin method 1)
Hematocrit (Hct)	Calculated as RBC × MCV/10 1)
Mean corpuscular volume (MCV)	Light scattering method 1)
Mean corpuscular hemoglobin (MCH)	Calculated as Hgb/RBC × 10 1)
Mean corpuscular hemoglobin concentration (MCHC)	Calculated as Hgb/Hct × 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	Enzymatic method (GLK·G-6-PDH)
T-cholesterol	Enzymatic method (CE·COD·POD) 3)
Triglyceride	Enzymatic method (LPL·GK·GPO·POD) 3)
Phospholipid	Enzymatic method (PLD·COD·POD) 3)
Glutamic oxaloacetic transaminase (GOT)	UV•Rate method 3)
Glutamic pyruvic transaminase (GPT)	UV·Rate method 3)
Lactate dehydrogenase (LDH)	UV·Rate method 3)
Alkaline phosphatase (ALP)	p-Nitrophenylphosphate method 3)
γ -Glutamyl transpeptidase (γ -GTP)	L- γ -Glutamyl-p-nitroanilide method 3)
Creatine phosphokinase (CPK)	UV•Rate method 3)
Urea nitrogen	Enzymatic method (Urease · GLDH) 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	Enzymatic method (PNP·XOD·POD) 3)
Urinalysis	
PH,Protein,Glucose,Ketone body,Bilirubin,Occult Blood,	Urinalysis reagent paper method 4)
Urobilinogen	

- 1) Automatic blood cell analyzer (Technicon H·1: Technicon Instruments Corporation, USA)
- 2) Automatic blood cell differential analyzer (Hitachi 8200: Hitachi, Ltd., Japan)
- 3) Automatic analyzer (Hitachi 7070: Hitachi, Ltd., Japan)
- 4) Ames reagent strips for urinalysis (Multistix: Bayer-Sankyo Co.,Ltd.,Japan)

APPENDIX Q 2

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-YEAR IANHALAION STUDY OF DICHLOROMEHANE

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-YEAR INHALATION STUDY OF DICHLOROMETHANE

Item	Unit	Decimal place
Hematology		
Red blood cell (RBC)	$\times 10^6/\mu$ 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	$\times 10^3/\mu$ L	0
White blood cell (WBC)	$\times 10^3/\mu$ 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 transminase (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