

*N,N*-ジメチルホルムアミドのラットを用いた  
吸入によるがん原性試験報告書

試験番号：0296

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(A1～Q2)

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APPENDIX A 1

CLINICAL OBSERVATION: SUMMARY, RAT: MALE

( 2-YEAR STUDY )

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : MALE

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Clinical sign	Group Name	Administration Week-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	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	1	1	1	1	1	1	1	2	2	2	2	2	3
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
LATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0



STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrJ  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : MALE

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Clinical sign	Group Name	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
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	3	3	3	3	3	3	3	3	3	3	3	3	3	3
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : MALE

PAGE : 3

Clinical sign	Group Name	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
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	3	3	3	3	3	3	3	3	3	3	3	3	3	3
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	1
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
LATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : MALE

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Clinical sign	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
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	1	1	1	1	1	1	1	1	1	1	2	2	2	2
	400 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	800 ppm	3	3	3	3	3	3	3	3	3	3	3	3	3	3
MORIBUND SACRIFICE	Control	0	0	0	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : MALE

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Clinical sign	Group Name	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
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	400 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	800 ppm	3	3	3	3	3	3	3	3	3	3	3	3	3	3
MORIBUND SACRIFICE	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	1	1	1	1	1	1
	800 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
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Clinical sign	Group Name	Administration Week-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	0	0	0	0	0	1	1	1	1	1	1	1	1
	200 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	400 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	800 ppm	3	3	4	4	4	4	4	4	4	4	4	4	4	4
MORIBUND SACRIFICE	Control	1	1	1	1	1	1	1	1	1	1	1	1	2	2
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	400 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	800 ppm	1	1	1	1	1	1	2	2	2	2	2	2	2	2
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	1	1	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
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Clinical sign	Group Name	Administration Week-day													
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	Control	1	1	1	1	1	1	1	1	1	1	1	1	2	3
	200 ppm	2	2	3	3	3	4	4	5	5	5	5	6	6	6
	400 ppm	2	2	2	2	2	2	2	3	3	3	4	4	4	4
	800 ppm	4	4	4	4	4	4	5	5	5	5	5	5	5	6
MORIBUND SACRIFICE	Control	3	3	3	3	3	3	3	3	3	3	3	3	3	4
	200 ppm	1	1	2	2	2	2	2	2	2	2	2	2	3	3
	400 ppm	1	1	1	1	1	1	1	2	2	2	2	2	3	3
	800 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
LOCOMOTOR MOVEMENT DECR	Control	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	1	0	0	0	0	0	0	0	0	0	1	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	1	1	1	1	1	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	1	0	1	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	1	1	1	1	1	0	0	0	0	0	0	0	1	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

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Clinical sign	Group Name	Administration 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	3	3	4	4	4	4	4
	200 ppm	6	7	7	7	7	7	7
	400 ppm	4	4	5	5	5	5	5
	800 ppm	7	7	7	7	8	9	9
MORIBUND SACRIFICE	Control	4	4	4	4	4	4	4
	200 ppm	3	3	3	5	5	5	5
	400 ppm	3	3	4	4	4	4	5
	800 ppm	2	2	3	3	4	4	4
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	2	0	0	0
	400 ppm	0	0	1	0	0	0	1
	800 ppm	0	0	1	0	0	0	0
LATERAL	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	2	0	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0
PARALYTIC GAIT	Control	0	1	1	0	0	0	0
	200 ppm	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0
	200 ppm	0	1	1	2	1	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0
	200 ppm	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
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Clinical sign	Group Name	Administration Week-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
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
CATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ORAL CAVITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0



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Clinical sign	Group Name	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
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	1	1	2	2
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
CATARACT	Control	0	0	0	0	0	0	0	0	0	0	1	1	2	2
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ORAL CAVITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
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CLINICAL OBSERVATION (SUMMARY)  
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Clinical sign	Group Name	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
EYE OPACITY	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
CATARACT	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ORAL CAVITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1 104

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Clinical sign	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
EYE OPACITY	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	200 ppm	1	1	1	1	1	1	1	1	1	1	1	2	2	2
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
CATARACT	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	200 ppm	1	1	1	1	1	1	1	1	1	1	1	2	2	2
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
EXTERNAL MASS	Control	0	0	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ORAL CAVITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.EAR	Control	0	0	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
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Clinical sign	Group Name	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
EYE OPACITY	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	200 ppm	2	2	2	2	2	2	2	2	3	3	3	3	3	3
	400 ppm	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	800 ppm	1	1	1	1	1	1	2	2	2	2	2	2	2	2
CATARACT	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	200 ppm	2	2	2	2	2	2	2	2	3	3	3	3	3	3
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	1	1	1	1	1	1	2	2	2	2	2	2	2	2
EXTERNAL MASS	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	0	0	1	1	1	1	1	1	1	1	1	1	1	2
	400 ppm	0	0	1	2	2	2	2	2	2	1	1	1	1	1
	800 ppm	0	1	1	1	1	1	1	1	1	1	2	2	2	2
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	1	1	1	1	1	1	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ORAL CAVITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.EAR	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
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Clinical sign	Group Name	Administration Week-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
EYE OPACITY	Control	2	2	2	2	3	3	4	4	4	4	4	4	4	4
	200 ppm	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	2	2	2	2	2	2	2	2	2	2	3	3	3	3
CATARACT	Control	2	2	2	2	3	3	4	4	4	4	4	4	4	4
	200 ppm	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	2	2	2	2	2	2	2	2	2	2	3	3	3	3
EXTERNAL MASS	Control	1	1	1	1	2	2	2	2	2	2	3	3	3	3
	200 ppm	2	2	3	3	5	5	5	5	5	4	5	5	6	6
	400 ppm	1	1	1	2	2	2	2	2	3	3	3	3	3	3
	800 ppm	2	2	1	1	1	1	1	1	1	1	1	1	1	1
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	1	1	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ORAL CAVITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.EAR	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
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Clinical sign	Group Name	Administration Week-day													
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
EYE OPACITY	Control	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	200 ppm	3	3	3	3	3	3	3	3	3	3	3	4	4	4
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	800 ppm	3	3	3	3	3	3	3	3	3	3	3	3	3	3
CATARACT	Control	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	200 ppm	3	3	3	3	3	3	3	3	3	3	3	4	4	4
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	800 ppm	3	3	3	3	3	3	3	3	3	3	3	3	3	3
EXTERNAL MASS	Control	4	4	4	4	4	3	3	3	5	5	5	6	5	5
	200 ppm	6	6	6	5	7	6	6	5	6	7	7	8	8	7
	400 ppm	3	3	3	3	3	3	3	4	4	4	4	4	4	4
	800 ppm	1	1	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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
M.NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.PERI MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ORAL CAVITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	1	2	1	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.EAR	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1 104

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Clinical sign	Group Name	Administration 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	4	4	4	4	4	4	4
	200 ppm	4	4	4	4	4	4	4
	400 ppm	1	1	2	2	2	2	2
	800 ppm	3	3	3	3	3	2	2
CATARACT	Control	4	4	4	4	4	4	4
	200 ppm	4	4	4	4	4	4	4
	400 ppm	1	1	2	2	2	2	2
	800 ppm	3	3	3	3	3	2	2
EXTERNAL MASS	Control	5	6	6	6	7	7	8
	200 ppm	8	7	8	9	9	8	8
	400 ppm	5	5	6	6	6	6	6
	800 ppm	2	2	2	2	1	1	2
INTERNAL MASS	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	1
	400 ppm	0	1	1	0	1	1	2
	800 ppm	0	0	0	0	0	0	1
M.NOSE	Control	0	0	0	0	0	0	0
	200 ppm	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0
M.PERI MOUTH	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	1	1	1
	800 ppm	0	0	0	0	0	0	0
M.ORAL CAVITY	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0
M.EAR	Control	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0

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ANIMAL : RAT F344/DuCrj  
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Clinical sign	Group Name	Administration Week-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.PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0



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Clinical sign	Group Name	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
M.PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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Clinical sign	Group Name	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
M.PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

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Clinical sign	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
M.PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

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Clinical sign	Group Name	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.PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	1	1	1	1	1	1	1	1	1	1	1	1
	800 ppm	0	1	1	1	1	1	1	1	1	1	2	2	2	2
M.POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	1	1	1	1	1	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

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Clinical sign	Group Name	Administration Week-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
M.PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.BREAST	Control	0	0	0	0	0	0	0	0	0	0	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	1	1	1	1	1	1	1	1	1	1	1
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ABDOMEN	Control	0	0	0	0	1	1	1	0	0	0	0	0	0	0
	200 ppm	0	0	1	1	1	1	1	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	1	1	1	1	1	1
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	400 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	800 ppm	2	2	1	1	1	1	1	1	1	1	1	1	1	1
M.POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	200 ppm	1	1	1	1	3	3	3	3	3	2	2	2	2	2
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

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Clinical sign	Group Name	Administration Week-day													
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M.PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	1	1	1	1	1	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.BREAST	Control	1	1	1	1	1	1	1	1	1	1	1	2	2	2
	200 ppm	0	0	1	1	1	1	1	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ABDOMEN	Control	2	2	2	2	2	1	1	1	1	1	1	1	1	1
	200 ppm	1	1	1	1	2	2	2	1	1	2	2	2	2	2
	400 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	1	1	1	1	1	1
	200 ppm	1	1	1	1	1	1	1	1	2	2	2	2	2	2
	400 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	800 ppm	1	1	1	2	2	2	2	2	2	2	2	2	2	2
M.POSTERIOR DORSUM	Control	1	1	1	1	1	1	1	1	1	1	1	1	0	0
	200 ppm	2	2	2	1	1	1	1	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	0
	400 ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.GENITALIA	Control	0	0	0	0	0	0	0	0	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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ANIMAL : RAT F344/DuCrj  
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Clinical sign	Group Name	Administration Week-day						
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
		1	1	1	1	1	1	1
M.PERI EAR	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0
M.NECK	Control	0	0	0	0	0	0	0
	200 ppm	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0
M.BREAST	Control	2	2	2	2	3	4	4
	200 ppm	1	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	1
M.ABDOMEN	Control	1	1	1	1	1	1	1
	200 ppm	2	2	3	4	3	3	3
	400 ppm	1	1	1	1	1	1	1
	800 ppm	0	0	0	0	0	0	0
M.ANTERIOR.DORSUM	Control	1	1	1	1	2	2	3
	200 ppm	2	2	2	2	3	2	2
	400 ppm	1	1	1	1	1	1	1
	800 ppm	2	2	2	2	1	1	1
M.POSTERIOR DORSUM	Control	0	0	0	0	0	0	0
	200 ppm	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0
M.HINDLIMB	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0
	400 ppm	1	1	1	1	1	1	1
	800 ppm	0	0	0	0	0	0	0
M.GENITALIA	Control	1	2	2	2	2	1	1
	200 ppm	0	0	0	0	0	0	0
	400 ppm	0	0	1	1	1	1	1
	800 ppm	0	0	0	0	0	0	0

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Clinical sign	Group Name	Administration Week-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.SCROTUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.TAIL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0



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Clinical sign	Group Name	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
M.SCROTUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.TAIL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
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Clinical sign	Group Name	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
M.SCROTUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.TAIL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
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SEX : MALE

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Clinical sign	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
M.SCROTUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.TAIL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
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Clinical sign	Group Name	Administration Week-day				59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7
		56-7	57-7	58-7												
		1	1	1		1	1	1	1	1	1	1	1	1	1	1
M.SCROTUM	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
M.TAIL	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRATION	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
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Clinical sign	Group Name	Administration Week-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
M.SCROTUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.TAIL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	1	1	1	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
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SEX : MALE

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Clinical sign	Group Name	Administration Week-day													
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M.SCROTUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.TAIL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	1	1	0	0	0	0	0	0	0	0	0	1	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	1	1	0	0	0	0	0	0	0	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	1	1	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
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SEX : MALE

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Clinical sign	Group Name	Administration Week-day						
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
		1	1	1	1	1	1	1
M.SCROTUM	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0
	400 ppm	1	1	1	1	1	1	1
	800 ppm	0	0	0	0	0	0	0
M.TAIL	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0
	400 ppm	1	1	1	1	0	0	0
	800 ppm	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	1	0	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0
JAUNDISE	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0
	400 ppm	0	1	1	0	0	0	1
	800 ppm	0	0	0	1	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0
	200 ppm	0	0	1	2	0	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	1	0	0	0	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0
	200 ppm	0	0	1	2	0	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	1	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	1	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	1	0	0	0
	400 ppm	0	0	1	0	0	0	1
	800 ppm	0	0	1	0	0	0	0

APPENDIX A 2

CLINICAL OBSERVATION: SUMMARY, RAT: FEMALE

( 2-YEAR STUDY )



STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

PAGE : 33

Clinical sign	Group Name	Administration Week-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	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	1	4	4	4	4	4	4	4	5	5	5	6	6
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

PAGE : 34

Clinical sign	Group Name	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
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	6	6	7	7	7	8	9	10	10	10	10	10	10	10
MORBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	2	2	2	2	2	2
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

PAGE : 35

Clinical sign	Group Name	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
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	10	10	11	11	11	11	11	11	11	11	11	11	11	11
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EYE OPACITY	Control	1	1	2	2	2	2	2	2	2	2	2	2	2	2
	200 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

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Clinical sign	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
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	1
	800 ppm	11	11	11	11	11	11	11	11	11	11	11	11	12	13
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EYE OPACITY	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	200 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	400 ppm	0	0	0	0	0	1	1	1	1	1	1	1	1	1
	800 ppm	1	1	2	2	2	2	2	2	2	2	2	2	2	2

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

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Clinical sign	Group Name	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
DEATH	Control	0	0	0	0	0	0	0	0	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	800 ppm	13	13	13	13	13	13	13	13	13	13	13	13	14	14
MORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EYE OPACITY	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	200 ppm	2	2	3	3	3	3	3	3	3	3	3	3	3	3
	400 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	800 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

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Clinical sign	Group Name	Administration Week-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	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	1	1	1	1	2	3
	400 ppm	2	2	2	2	2	2	2	3	3	3	3	3	3	3
	800 ppm	14	14	14	14	14	14	14	14	14	14	14	14	14	14
MORIBUND SACRIFICE	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	2
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EYE OPACITY	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	200 ppm	3	3	3	3	4	4	4	4	4	4	4	4	4	4
	400 ppm	1	1	1	1	1	1	2	3	3	3	3	3	3	3
	800 ppm	2	2	2	2	2	2	3	3	3	3	3	3	3	3

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

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Clinical sign	Group Name	Administration Week-day													
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	3	3	4	4	5	5	5	5	5	5	5	5	5	5
	400 ppm	3	3	3	4	5	5	5	5	5	5	5	5	5	5
	800 ppm	14	14	15	15	15	15	16	16	16	16	16	16	16	16
MORIBUND SACRIFICE	Control	2	2	2	2	2	2	2	2	2	2	2	3	3	3
	200 ppm	0	1	1	1	2	2	2	2	2	2	2	2	3	3
	400 ppm	2	2	2	2	2	2	2	2	3	3	4	4	4	4
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	200 ppm	0	0	0	0	1	0	0	0	0	0	0	0	1	0
	400 ppm	0	0	0	0	0	0	0	0	1	0	1	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	200 ppm	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	800 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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EYE OPACITY	Control	2	2	2	2	2	2	2	2	3	3	3	3	3	3
	200 ppm	4	4	4	4	3	3	3	3	3	3	3	3	3	3
	400 ppm	3	3	3	3	3	3	3	3	3	4	4	4	4	4
	800 ppm	3	3	3	3	3	3	3	3	3	3	3	3	3	3

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Clinical sign	Group Name	Administration 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
	200 ppm	5	5	5	5	5	5	7
	400 ppm	5	5	5	5	5	5	5
	800 ppm	16	16	16	16	16	17	18
MORIBUND SACRIFICE	Control	3	3	3	3	4	4	5
	200 ppm	3	4	4	4	4	4	5
	400 ppm	5	5	5	5	5	5	7
	800 ppm	0	1	1	2	2	2	2
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	1
	200 ppm	0	0	0	0	0	0	0
	400 ppm	1	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0
	200 ppm	0	1	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0
	400 ppm	1	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	1
	200 ppm	0	0	0	0	0	1	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0
	400 ppm	1	1	1	1	1	1	1
	800 ppm	0	0	0	0	0	0	0
EYE OPACITY	Control	3	3	3	3	4	4	4
	200 ppm	3	3	3	3	3	3	3
	400 ppm	4	4	4	4	4	4	6
	800 ppm	3	3	3	3	3	3	3



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Clinical sign	Group Name	Administration Week-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
CATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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Clinical sign	Group Name	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
CATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	2	2	2	2	2	2
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	1
M.NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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Clinical sign	Group Name	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
CATARACT	Control	1	1	2	2	2	2	2	2	2	2	2	2	2	2
	200 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	1	1	0	0	0	0	0	0	0	0	0	0	0	0
M.NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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Clinical sign	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
CATARACT	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	200 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	400 ppm	0	0	0	0	0	1	1	1	1	1	1	1	1	1
	800 ppm	1	1	2	2	2	2	2	2	2	2	2	2	2	2
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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Clinical sign	Group Name	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
CATARACT	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	200 ppm	2	2	3	3	3	3	3	3	3	3	3	3	3	3
	400 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	800 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	1	1	0	0	0	2
	200 ppm	1	1	1	2	2	2	2	2	2	2	2	2	2	2
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
INTERNAL MASS	Control	0	0	0	0	0	0	1	1	0	0	1	1	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.PERI EAR	Control	0	0	0	0	0	0	0	0	1	1	0	0	0	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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Clinical sign	Group Name	Administration Week-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
CATARACT	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	200 ppm	3	3	3	3	4	4	4	4	4	4	4	4	4	4
	400 ppm	1	1	1	1	1	1	2	3	3	3	3	3	3	3
	800 ppm	2	2	2	2	2	2	3	3	3	3	3	3	3	3
EXTERNAL MASS	Control	2	2	2	2	2	3	3	2	2	2	4	5	5	5
	200 ppm	2	2	2	2	2	2	2	2	1	1	2	2	3	3
	400 ppm	0	0	1	0	1	1	1	1	1	1	1	1	1	1
	800 ppm	1	2	2	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
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	1	1	1	1	1	1	1	1	1	1	1	1	1
M.MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.PERI EAR	Control	1	0	0	0	0	0	0	0	0	0	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NECK	Control	1	1	1	1	1	1	1	0	0	0	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
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Clinical sign	Group Name	Administration Week-day													
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
CATARACT	Control	2	2	2	2	2	2	2	2	3	3	3	3	3	3
	200 ppm	4	4	4	4	3	3	3	3	3	3	3	3	3	3
	400 ppm	3	3	3	3	3	3	3	3	3	4	4	4	4	4
	800 ppm	3	3	3	3	3	3	3	3	3	3	3	3	3	3
EXTERNAL MASS	Control	4	4	4	4	4	4	5	6	6	6	6	7	7	8
	200 ppm	3	3	2	2	2	2	2	2	2	2	2	2	5	5
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	800 ppm	2	2	2	2	2	2	3	3	3	3	3	3	3	3
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	1	3	2
	400 ppm	0	0	0	0	0	0	0	1	3	2	2	2	2	2
	800 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
M.NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
M.MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.NECK	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

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Clinical sign	Group Name	Administration Week-day						
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
		1	1	1	1	1	1	1
CATARACT	Control	3	3	3	3	4	4	4
	200 ppm	3	3	3	3	3	3	3
	400 ppm	4	4	4	4	4	4	4
	800 ppm	3	3	3	3	3	3	3
EXTERNAL MASS	Control	7	7	7	7	6	7	7
	200 ppm	5	5	4	4	5	5	4
	400 ppm	1	1	0	0	1	1	2
	800 ppm	3	3	2	2	3	3	3
INTERNAL MASS	Control	0	0	0	0	1	1	1
	200 ppm	2	2	1	1	2	2	0
	400 ppm	2	2	2	2	2	4	2
	800 ppm	2	3	2	2	1	1	3
M.NOSE	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	1	1	1	1	1	1	1
M.MANDIBULAR	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0
M.EAR	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	1	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0
M.PERI EAR	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0
	400 ppm	1	1	0	0	1	1	1
	800 ppm	0	0	0	0	0	0	0
M.NECK	Control	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0



STUDY NO. : 0296  
ANIMAL : RAT F344/DuGrj  
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Clinical sign	Group Name	Administration Week-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.BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

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Clinical sign	Group Name	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
M.BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

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Clinical sign	Group Name	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
M.BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
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Clinical sign	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
M.BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

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Clinical sign	Group Name	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.BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	1	1	1	1	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
M.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

PAGE : 54

Clinical sign	Group Name	Administration Week-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
M.BREAST	Control	0	0	0	0	0	1	1	1	1	1	1	2	2	2
	200 ppm	0	0	0	0	0	0	0	0	0	0	1	1	2	2
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	1	1	1	1	1	1	1	1	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
M.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.POSTERIOR DORSUM	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400 ppm	0	0	1	0	1	1	1	1	1	1	1	1	1	1
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

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Clinical sign	Group Name	Administration Week-day													
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M.BREAST	Control	2	2	2	2	2	2	2	3	3	3	3	3	2	3
	200 ppm	2	2	2	2	2	2	2	2	2	2	2	2	4	4
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.ABDOMEN	Control	0	0	0	0	0	0	1	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	1	1	1	1	1	1	2	2	2	3	3	3	3	3
M.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
M.POSTERIOR DORSUM	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	1	2	2
	200 ppm	1	1	0	0	0	0	0	0	0	0	0	0	1	1
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

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Clinical sign	Group Name	Administration Week-day						
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
		1	1	1	1	1	1	1
M.BREAST	Control	2	2	2	2	2	2	2
	200 ppm	4	5	4	4	4	4	3
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0
M.ABDOMEN	Control	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	3	3	2	2	2	2	2
M.ANTERIOR.DORSUM	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	1	1	0	0	0	0	0
M.POSTERIOR DORSUM	Control	1	1	1	1	1	1	1
	200 ppm	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0
M.GENITALIA	Control	2	2	2	2	1	2	2
	200 ppm	1	1	0	0	0	1	1
	400 ppm	0	0	0	0	0	0	1
	800 ppm	0	0	0	0	1	1	1
ANEMIA	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0
	400 ppm	1	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0
JAUNDISE	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	1	0
	400 ppm	0	0	0	0	1	2	1
	800 ppm	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	1
	200 ppm	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	1
	800 ppm	0	0	0	1	0	0	0



STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
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SEX : FEMALE

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Clinical sign	Group Name	Administration Week-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
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS3

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

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Clinical sign	Group Name	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
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
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CLINICAL OBSERVATION (SUMMARY)  
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SEX : FEMALE

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Clinical sign	Group Name	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
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

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Clinical sign	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
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
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CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

PAGE : 61

Clinical sign	Group Name	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
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
 ALL ANIMALS

SEX : FEMALE

PAGE : 62

Clinical sign	Group Name	Administration Week-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
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuGrj  
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
 ALL ANIMALS

SEX : FEMALE

PAGE : 63

Clinical sign	Group Name	Administration Week-day													
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	800 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
 ALL ANIMALS

SEX : FEMALE

PAGE : 64

Clinical sign	Group Name	Administration Week-day						
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
		1	1	1	1	1	1	1
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	1
	200 ppm	0	0	0	0	0	0	0
	400 ppm	1	0	0	0	0	0	1
	800 ppm	0	0	0	1	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0
	400 ppm	1	0	0	0	0	0	0
	800 ppm	0	0	0	1	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	1
	200 ppm	0	0	0	0	0	0	0
	400 ppm	0	0	0	0	0	0	0
	800 ppm	0	1	0	0	0	0	0

(HAN190)

BAIS3



APPENDIX B 1

BODY WEIGHT CHANGES: SUMMARY, RAT: MALE

( 2-YEAR STUDY )

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 1

Group Name	Administration week-day													
	0-0		1-1		1-7		2-7		3-7		4-7		5-7	
Control	128±	5	132±	5	157±	7	186±	9	210±	10	230±	10	245±	11
200 ppm	128±	5	132±	5	152±	8*	185±	10	211±	12	231±	13	247±	14
400 ppm	128±	5	133±	5	143±	7**	168±	9**	192±	9**	210±	10**	229±	10**
800 ppm	128±	5	132±	5	140±	8**	152±	13**	175±	14**	187±	15**	201±	16**

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuGrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 2

Group Name	Administration		week-day									
	6-7		7-7		8-7		9-7		10-7		11-7	
Control	259±	11	272±	12	285±	13	295±	14	304±	14	311±	15
200 ppm	260±	15	273±	15	286±	15	297±	15	307±	15	314±	17
400 ppm	236±	12**	245±	11**	253±	12**	262±	12**	269±	13**	278±	13**
800 ppm	208±	14**	214±	16**	219±	16**	225±	17**	231±	17**	245±	17**

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 3

Group Name	Administration		week-day									
	13-7		14-7		18-7		22-7		26-7		30-7	
Control	323±	15	329±	15	348±	16	362±	18	376±	19	385±	19
200 ppm	325±	19	330±	19	347±	18	361±	20	374±	21	384±	23
400 ppm	284±	15**	285±	14**	297±	15**	310±	16**	319±	17**	330±	19**
800 ppm	252±	18**	249±	19**	262±	19**	276±	19**	280±	22**	292±	22**

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

Test of Dunnett

(HAN260)

BAIS3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 4

Group Name	Administration		week-day									
	38-7		42-7		46-7		50-7		54-7		58-7	
Control	402±	21	410±	22	415±	22	420±	23	423±	23	430±	21
200 ppm	398±	24	405±	24	410±	24	413±	23	414±	22	418±	23*
400 ppm	343±	21**	353±	19**	357±	19**	360±	20**	362±	20**	364±	20**
800 ppm	309±	22**	314±	23**	315±	23**	320±	23**	318±	25**	318±	25**

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 5

Group Name	Administration		week-day											
	66-7		70-7		74-7		78-7		82-7		86-7		90-7	
Control	435±	24	436±	25	435±	24	435±	25	433±	24	430±	24	426±	25
200 ppm	422±	22*	421±	22**	419±	20**	417±	23**	415±	25**	410±	29**	408±	28
400 ppm	371±	20**	374±	20**	376±	20**	372±	20**	373±	23**	368±	20**	365±	19**
800 ppm	322±	22**	322±	24**	328±	24**	321±	22**	324±	20**	317±	21**	317±	20**

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0296  
ANIMAL : RAT F344/DuGrj  
UNIT : g  
REPORT TYPE : A1 104  
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 6

Group Name	Administration week-day							
	94-7		98-7		102-7		104-7	
Control	419±	30	409±	33	400±	37	393±	41
200 ppm	393±	25	381±	32*	374±	24*	366±	29*
400 ppm	357±	21**	351±	18**	346±	19**	340±	25**
800 ppm	313±	20**	306±	19**	303±	19**	299±	18**

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

Test of Dunnett

(HAN260)

BAIS 3

APPENDIX B 2

BODY WEIGHT CHANGES: SUMMARY, RAT: FEMALE

( 2-YEAR STUDY )



STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 7

Group Name	Administration		week-day									
	0-0		1-1		1-7		2-7		3-7		4-7	
Control	99±	3	101±	4	112±	4	124±	5	135±	5	144±	6
200 ppm	99±	3	100±	3	105±	4**	122±	5	133±	5	140±	6*
400 ppm	99±	3	101±	3	99±	4**	111±	6**	121±	6**	127±	8**
800 ppm	99±	3	101±	3	100±	6**	102±	6**	114±	6**	117±	8**

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

Test of Dunnett

(HAN260)

BAIS3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 8

Group Name	Administration		week-day									
	6-7		7-7		8-7		9-7		10-7		11-7	
Control	157±	8	162±	8	166±	9	171±	10	176±	10	180±	11
200 ppm	151±	7**	156±	9**	160±	8**	165±	10**	168±	10**	173±	10*
400 ppm	138±	8**	141±	8**	144±	9**	146±	11**	150±	10**	155±	9**
800 ppm	124±	10**	125±	11**	124±	12**	124±	12**	124±	13**	138±	13**

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuGrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 9

Group Name	Administration		week-day									
	13-7		14-7		18-7		22-7		26-7		30-7	34-7
Control	186± 11		187± 12		196± 12		202± 12		207± 13		214± 13	220± 16
200 ppm	175± 10**		177± 10**		181± 10**		188± 10**		192± 11**		197± 11**	202± 12**
400 ppm	159± 10**		158± 10**		162± 9**		170± 8**		174± 8**		179± 9**	184± 9**
800 ppm	138± 13**		135± 13**		140± 15**		147± 15**		148± 15**		155± 13**	153± 13**

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 10

Group Name	Administration		week-day									
	38-7		42-7		46-7		50-7		54-7		58-7	
Control	220±	14	226±	15	232±	17	236±	16	240±	18	248±	20
200 ppm	204±	12**	209±	14**	214±	14**	216±	15**	219±	15**	224±	17**
400 ppm	187±	10**	190±	10**	191±	10**	192±	13**	197±	10**	200±	10**
800 ppm	152±	12**	155±	14**	157±	13**	161±	15**	165±	16**	165±	14**

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 11

Group Name	Administration		week-day									
	66-7		70-7		74-7		78-7		82-7		86-7	
Control	258±	22	264±	23	269±	23	272±	25	277±	27	281±	25
200 ppm	234±	18**	241±	19*	242±	19**	245±	18**	250±	20*	253±	20*
400 ppm	204±	11**	206±	12**	212±	11**	209±	13**	213±	16**	217±	13**
800 ppm	178±	15**	184±	15**	191±	13**	187±	13**	193±	15**	193±	16**

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 12

Group Name	Administration week-day							
	94-7		98-7		102-7		104-7	
Control	289±	27	287±	24	284±	26	277±	32
200 ppm	258±	21**	258±	24**	259±	30*	254±	25
400 ppm	218±	15**	217±	16**	218±	19**	213±	21**
800 ppm	198±	17**	196±	16**	198±	14**	196±	13**

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

Test of Dunnett

(HAN260)

BAIS 3

## APPENDIX C 1

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 1

Group Name	Administration week-day(effective)						
	1-7(6)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	16.5± 1.2	16.7± 1.3	17.2± 1.1	17.4± 1.1	17.3± 1.0	16.9± 1.0	17.5± 1.1
200 ppm	15.3± 1.1**	16.6± 1.2	17.6± 1.3	17.4± 1.4	17.8± 1.3	17.2± 1.3	17.8± 1.5
400 ppm	13.9± 1.2**	15.5± 1.3**	17.0± 1.3	17.0± 1.5	18.1± 1.8	16.1± 1.4**	17.1± 1.9
800 ppm	13.4± 1.4**	12.0± 2.2**	14.9± 1.8**	14.3± 2.2**	15.2± 1.9**	15.2± 1.5**	15.6± 2.2**

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

Test of Dunnett

(HAN260)

BAIS3



STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 2

Group Name	Administration 8-7(7)	week-day(effective) 9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	14-7(7)
Control	17.6± 1.1	17.8± 1.0	17.7± 1.1	17.3± 1.0	17.1± 1.0	17.6± 1.1	17.0± 1.0
200 ppm	17.9± 1.4	18.1± 1.3	17.7± 1.2	17.6± 1.5	17.0± 1.3	17.6± 1.4	16.8± 1.4
400 ppm	17.7± 1.8	18.2± 2.1	17.7± 1.9	17.5± 1.6	16.2± 1.8*	18.6± 2.1	16.7± 2.0
800 ppm	15.4± 2.2**	14.8± 1.9**	14.7± 1.9**	16.2± 1.5**	14.6± 1.7**	15.2± 1.7**	13.9± 2.0**

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

Test of Dunnett

(HAN260)

BAIS3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 3

Group Name	Administration week-day(effective)						
	18-7(7)	22-7(7)	26-7(7)	30-7(7)	34-7(7)	38-7(7)	42-7(7)
Control	17.3± 1.0	17.6± 1.1	17.6± 1.1	17.6± 1.0	17.7± 1.0	17.4± 1.1	17.5± 1.1
200 ppm	17.0± 1.3	17.8± 1.5	17.9± 1.4	17.9± 1.5	17.9± 1.4	17.8± 1.5	17.7± 1.2
400 ppm	16.5± 2.1**	17.6± 2.3	17.0± 1.9*	17.8± 2.3	17.5± 1.9	17.3± 1.9	16.3± 1.3**
800 ppm	15.6± 1.8**	16.4± 1.5**	15.9± 1.7**	15.9± 1.7**	15.9± 1.6**	16.0± 1.3**	15.1± 1.5**
Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett							

(HAN260)

BAIS 3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 4

Group Name	Administration 46-7(7)	week-day(effective) 50-7(7)	54-7(7)	58-7(7)	62-7(7)	66-7(7)	70-7(7)
Control	17.6± 1.0	17.6± 1.0	17.9± 1.0	18.2± 1.2	17.9± 1.0	18.2± 1.3	18.0± 1.1
200 ppm	17.8± 1.4	17.6± 1.3	17.8± 1.3	18.0± 1.5	17.9± 1.1	17.5± 1.1	17.2± 1.2*
400 ppm	17.4± 1.6	17.9± 1.8	17.7± 1.7	17.7± 1.7*	17.3± 2.0*	17.9± 2.1	17.9± 2.1
800 ppm	15.9± 1.4**	16.5± 1.8**	16.0± 2.1**	16.1± 2.0**	16.3± 1.4**	15.7± 1.7**	16.6± 2.2**

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 5

Group Name	Administration week-day(effective)					
	74-7(7)	78-7(7)	82-7(7)	86-7(7)	90-7(7)	94-7(7)
Control	17.5± 1.4	17.4± 1.9	17.8± 1.7	17.0± 1.3	17.5± 1.5	17.6± 1.7
200 ppm	17.7± 1.3	17.2± 1.7	17.6± 1.4	17.3± 1.6	17.1± 1.8	18.1± 3.0
400 ppm	18.3± 2.0	17.7± 2.2	17.8± 2.6	17.7± 2.5	17.4± 2.3	18.3± 3.0
800 ppm	17.4± 2.3	16.1± 1.7**	16.3± 1.9**	16.1± 2.2**	16.1± 1.8**	17.1± 2.2

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
UNIT : g  
REPORT TYPE : A1 104  
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 6

Group Name	Administration week-day(effective)	
	102-7(7)	104-7(7)
Control	18.0± 1.6	17.8± 2.1
200 ppm	18.4± 2.4	18.5± 3.2
400 ppm	17.9± 2.2	17.7± 3.1
800 ppm	17.2± 2.2	17.0± 1.6*

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

Test of Dunnett

(HAN260)

BAIS3

## APPENDIX C 2

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 7

Group Name	Administration week-day(effective) 1-7(6)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	11.8± 0.7	11.4± 0.7	11.8± 0.7	11.7± 0.8	11.8± 0.8	11.7± 0.8	12.0± 0.9
200 ppm	10.3± 0.8**	11.6± 0.8	11.5± 0.7	11.4± 0.7	11.5± 1.1	11.0± 1.1**	11.6± 1.2
400 ppm	9.1± 0.7**	9.7± 0.8**	10.6± 0.7**	10.2± 1.1**	11.5± 1.4	9.8± 1.1**	10.5± 1.3**
800 ppm	9.3± 1.2**	7.7± 1.4**	10.5± 0.7**	8.8± 1.1**	8.8± 1.2**	8.8± 1.2**	8.8± 1.3**

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

Test of Dunnett

(HAN260)

BAIS3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 8

Group Name	Administration week-day(effective)						
	8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	14-7(7)
Control	11.8± 1.1	11.9± 1.2	12.0± 1.2	12.0± 1.5	11.9± 1.1	12.2± 1.2	11.8± 1.3
200 ppm	11.4± 1.3	11.5± 1.8	11.9± 1.9	12.2± 2.2	11.2± 1.4	11.7± 2.3*	11.4± 2.4*
400 ppm	10.4± 1.4**	10.6± 1.6**	10.3± 1.6**	10.9± 1.8**	9.5± 1.1**	10.8± 1.2**	9.8± 1.5**
800 ppm	8.4± 1.4**	7.9± 1.7**	8.0± 1.5**	10.3± 1.7**	8.0± 1.7**	9.4± 1.2**	8.3± 1.7**

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

Test of Dunnett

(HAN260)

BAIS3



STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 9

Group Name	Administration 18-7(7)	week-day(effective) 22-7(7)	26-7(7)	30-7(7)	34-7(7)	38-7(7)	42-7(7)
Control	11.9± 1.0	11.9± 1.2	12.1± 1.3	12.3± 1.1	12.5± 1.3	12.1± 0.9	12.1± 1.0
200 ppm	10.8± 1.6**	11.9± 2.0	11.5± 1.4	11.5± 0.9**	11.6± 1.3**	11.3± 1.1**	11.3± 1.2**
400 ppm	9.7± 1.2**	10.5± 1.2**	10.6± 1.3**	10.6± 1.2**	10.6± 1.3**	10.5± 1.0**	9.9± 0.9**
800 ppm	8.6± 1.7**	9.6± 1.3**	9.2± 1.1**	9.1± 1.3**	8.6± 1.4**	9.0± 1.0**	9.0± 1.0**

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 10

Group Name	Administration week-day(effective)						
	46-7(7)	50-7(7)	54-7(7)	58-7(7)	62-7(7)	66-7(7)	70-7(7)
Control	12.2± 1.1	12.2± 1.0	12.7± 1.1	13.3± 1.4	12.5± 1.9	12.9± 1.8	13.4± 1.2
200 ppm	11.2± 1.1**	11.2± 1.1**	11.7± 1.5**	12.0± 1.3**	12.4± 1.3	11.9± 1.2**	12.5± 1.0**
400 ppm	10.3± 0.9**	10.4± 1.6**	10.8± 1.2**	10.8± 1.0**	11.1± 1.1**	10.9± 1.3**	11.1± 1.3**
800 ppm	9.4± 1.4**	9.0± 1.6**	9.3± 2.0**	9.3± 1.4**	9.9± 1.1**	9.9± 1.4**	10.6± 1.1**

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

Test of Dunnett

(HAN260)

BAIS3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 11

Group Name	Administration 74-7(7)	week-day(effective) 78-7(7)	82-7(7)	86-7(7)	90-7(7)	94-7(7)	98-7(7)
Control	12.7± 1.4	12.7± 1.2	13.2± 1.7	12.9± 1.1	13.1± 1.2	13.9± 1.7	13.5± 1.2
200 ppm	12.4± 1.2	12.0± 1.1*	12.6± 1.1	12.3± 1.3	12.5± 1.1	12.8± 1.3**	12.8± 1.4
400 ppm	11.7± 1.2**	10.8± 1.0**	10.9± 1.8**	11.2± 1.2**	11.1± 1.2**	11.6± 1.8**	11.6± 1.7**
800 ppm	10.7± 1.2**	10.2± 1.4**	10.6± 1.5**	10.8± 1.8**	10.6± 1.5**	11.8± 1.5**	11.0± 1.9**

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

Test of Dunnett

(HAN260)

BAIS3

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
UNIT : g  
REPORT TYPE : A1 104  
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 12

Group Name	Administration week-day(effective)	
	102-7(7)	104-7(7)
Control	13.6± 2.2	13.1± 2.0
200 ppm	13.1± 2.1	12.9± 2.1
400 ppm	12.0± 2.0**	11.5± 2.3**
800 ppm	11.3± 1.6**	11.4± 1.3**

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

Test of Dunnett

(HAN260)

BAIS3

APPENDIX D 1

HEMATOLOGY: SUMMARY, RAT: MALE

( 2-YEAR STUDY )

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 MEASURE. TIME : 1  
 SEX : MALE

HEMATOLOGY (SUMMARY)  
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 10 <sup>6</sup> /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 <sup>3</sup> /μl	
Control	39	7.62±	1.37	12.1±	3.0	38.0±	7.6	49.9±	4.1	15.7±	1.9	31.4±	2.1	1048±	267
200 ppm	36	7.85±	1.65	12.1±	2.8	37.9±	7.3	48.7±	3.5	15.4±	1.4	31.6±	2.0	1094±	263
400 ppm	39	9.05±	1.28**	13.2±	1.7	40.9±	4.4	45.6±	3.4**	14.6±	0.7**	32.1±	1.1	971±	178
800 ppm	37	7.73±	1.45	11.5±	2.1	35.6±	5.9	46.5±	3.0**	14.9±	0.9	32.2±	1.9	1201±	280*

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS3

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
MEASURE. TIME : 1  
SEX : MALE

HEMATOLOGY (SUMMARY)  
ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	WBC 10 <sup>3</sup> /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	39	6.03±	2.00	1±	1	53±	8	1±	1	0±	0	4±	2	34±	8	7±	5
200 ppm	36	6.24±	1.97	1±	1	53±	8	1±	1	0±	0	4±	2	34±	8	7±	4
400 ppm	39	7.07±	8.24	1±	1	47±	11**	1±	1	0±	0	4±	2	39±	10*	8±	14
800 ppm	37	6.33±	1.59	1±	2	49±	9	1±	1	0±	0	4±	2	37±	8	8±	7

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS3

APPENDIX D 2

HEMATOLOGY: SUMMARY, RAT: FEMALE

( 2-YEAR STUDY )



STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 MEASURE. TIME : 1  
 SEX : FEMALE

HEMATOLOGY (SUMMARY)  
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	RED BLOOD CELL 10 <sup>6</sup> /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 <sup>3</sup> /μl	
Control	38	7.93±	1.27	14.5±	2.0	43.3±	5.0	55.4±	5.9	18.4±	1.6	33.3±	1.0	638±	148
200 ppm	38	8.42±	0.69	14.0±	1.2	42.0±	3.2	50.0±	2.6**	16.6±	1.0**	33.3±	1.2	689±	106
400 ppm	35	8.36±	1.67**	13.4±	2.4**	40.8±	6.9*	50.5±	10.1**	16.4±	2.3**	32.6±	1.3*	686±	162
800 ppm	28	8.35±	1.26*	12.9±	1.5**	39.5±	4.0**	48.3±	7.5**	15.7±	1.7**	32.6±	1.1*	764±	153**

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 MEASURE. TIME : 1  
 SEX : FEMALE

HEMATOLOGY (SUMMARY)  
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	WBC 10 <sup>3</sup> /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	38	6.26±	13.04	1±	1	46±	16	1±	1	0±	0	3±	2	39±	13	9±	18
200 ppm	38	4.30±	3.15	1±	1*	39±	16	1±	1	0±	0	3±	2	48±	14*	8±	9
400 ppm	35	4.57±	5.04	1±	3*	39±	11	1±	1	0±	0	3±	2	49±	13*	7±	7
800 ppm	28	8.50±	17.63	1±	2	39±	15	1±	1	0±	0	3±	2	44±	15	12±	22

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS3

APPENDIX E 1

BIOCHEMISTRY: SUMMARY, RAT: MALE

( 2-YEAR STUDY )

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 MEASURE. TIME : 1  
 SEX : MALE

BIOCHEMISTRY (SUMMARY)  
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	39	6.4±	0.4	3.2±	0.3	1.0±	0.1	0.16±	0.05	149±	17	179±	63	134±	131
200 ppm	36	6.5±	0.4	3.1±	0.3	0.9±	0.1	0.25±	0.10**	141±	23	309±	95**	296±	188**
400 ppm	39	6.7±	0.3**	3.4±	0.3**	1.1±	0.1**	0.33±	0.27**	144±	21	243±	59**	152±	83
800 ppm	37	6.4±	0.5	3.2±	0.3	1.0±	0.1	0.40±	0.26**	131±	20**	292±	72**	137±	96

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS3

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
MEASURE. TIME : 1  
SEX : MALE

BIOCHEMISTRY (SUMMARY)  
ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT IU/l		GPT IU/l		LDH IU/l		ALP IU/l		G-GTP IU/l		CPK IU/l	
Control	39	267±	89	73±	36	32±	16	174±	42	189±	71	8±	5	98±	45
200 ppm	36	427±	122**	128±	117	56±	36**	193±	127	330±	536	21±	15**	132±	250
400 ppm	39	340±	82**	195±	123**	96±	53**	201±	167	352±	122**	31±	12**	83±	14*
800 ppm	37	422±	94**	497±	1325**	195±	301**	850±	3844**	395±	145**	45±	20**	115±	81*

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

Test of Dunnett

(HCL074)

BAIS3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 MEASURE, TIME : 1  
 SEX : MALE

BIOCHEMISTRY (SUMMARY)  
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	UREA NITROGEN mg/dl		CREATININE mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	39	21.0±	6.8	0.6±	0.2	141±	1	3.9±	0.3	106±	2	10.2±	0.4	4.3±	0.8
200 ppm	36	26.9±	9.2**	0.6±	0.1	141±	2*	3.9±	0.3	106±	2	10.5±	0.5**	4.8±	1.0*
400 ppm	39	20.0±	3.3	0.5±	0.1	141±	1*	3.8±	0.3	106±	2	10.4±	0.2*	4.4±	0.5
800 ppm	37	25.2±	10.8*	0.5±	0.1	140±	1**	4.0±	0.4	106±	2	10.4±	0.4*	5.1±	1.8**

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS3

APPENDIX E 2

BIOCHEMISTRY: SUMMARY, RAT: FEMALE

( 2-YEAR STUDY )

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 MEASURE, TIME : 1  
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)  
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	38	6.9±	0.5	3.9±	0.3	1.3±	0.2	0.16±	0.08	132±	26	148±	62	83±	80
200 ppm	38	6.9±	0.3	3.8±	0.3	1.3±	0.2	0.19±	0.07**	137±	18	196±	40**	78±	51
400 ppm	35	6.8±	0.7	3.9±	0.4	1.3±	0.1	0.95±	4.52**	136±	22	212±	40**	87±	97
800 ppm	29	6.8±	0.4	3.8±	0.3	1.3±	0.2	0.29±	0.37**	136±	15	271±	59**	91±	64

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS3



STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 MEASURE. TIME : 1  
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)  
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 5

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT IU/l		GPT IU/l		LDH IU/l		ALP IU/l		G-GTP IU/l		CPK IU/l	
Control	38	265±	102	120±	87	56±	29	241±	151	125±	65	4±	3	87±	20
200 ppm	38	303±	61*	173±	123**	81±	36**	216±	92	148±	59	10±	7**	90±	42
400 ppm	35	331±	63**	158±	161	79±	62*	245±	265	208±	269*	13±	10**	91±	24
800 ppm	29	404±	82**	230±	175**	110±	75**	267±	218	306±	111**	104±	62**	108±	50*

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

Test of Dunnett

(HCL074)

BAIS3

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 MEASURE. TIME : 1  
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)  
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 6

Group Name	NO. of Animals	UREA NITROGEN mg/dl		CREATININE mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	38	17.1±	1.9	0.5±	0.1	141±	1	3.6±	0.4	104±	3	10.3±	0.4	3.8±	0.6
200 ppm	38	19.6±	5.5**	0.5±	0.1	141±	2	3.7±	0.4	105±	2	10.3±	0.3	3.9±	0.7
400 ppm	35	19.6±	2.9**	0.5±	0.1	140±	2	3.8±	0.4	105±	2	10.3±	0.4	4.1±	0.9
800 ppm	29	19.6±	3.0**	0.5±	0.1	141±	1	3.9±	0.3*	106±	2	10.3±	0.2	4.4±	1.0**

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS3

APPENDIX F1

URINALYSIS: SUMMARY, RAT: MALE

( 2-YEAR STUDY )

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 MEASURE. TIME : 1  
 SEX : MALE

# URINALYSIS

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	pH							CHI	Protein						CHI	Glucose						CHI	Ketone body						CHI	Bilirubin				CHI
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+	4+		-	±	+	2+	3+	4+		-	±	+	2+	3+	4+		-	+	2+	3+	
Control	42	0	3	5	12	12	8	2		0	0	1	2	37	2		42	0	0	0	0	0		37	5	0	0	0	0		40	2	0	0	
200 ppm	38	0	1	5	9	13	8	2		0	0	0	1	34	3		38	0	0	0	0	0		36	1	1	0	0	0		37	1	0	0	
400 ppm	41	0	1	2	5	12	11	10		0	0	0	3	34	4		41	0	0	0	0	0		22	15	4	0	0	0	**	35	4	0	2	
800 ppm	37	0	3	8	5	14	6	1		0	0	0	0	33	4		37	0	0	0	0	0		27	9	1	0	0	0		31	5	1	0	

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

Test of CHI SQUARE

(HCL101)

BAIS3

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
MEASURE. TIME : 1  
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Occult blood					Urobilinogen						
		-	±	+	2+	3+	CHI	±	+	2+	3+	4+	CHI
Control	42	38	3	1	0	0		42	0	0	0	0	
200 ppm	38	37	1	0	0	0		38	0	0	0	0	
400 ppm	41	41	0	0	0	0		40	1	0	0	0	
800 ppm	37	35	0	1	1	0		37	0	0	0	0	

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

Test of CHI SQUARE

(HCL101)

BAIS3

APPENDIX F 2

URINALYSIS: SUMMARY, RAT: FEMALE

( 2-YEAR STUDY )

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 MEASURE. TIME : 1  
 SEX : FEMALE

# URINALYSIS

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	pH							CHI	Protein					CHI	Glucose					CHI	Ketone body					CHI	Bilirubin				CHI		
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+		4+	-	±	+	2+		3+	4+	-	±	+		2+	3+	4+	-		+	2+
Control	43	0	5	8	5	12	11	2		0	1	9	13	12	8		43	0	0	0	0	0		36	6	1	0	0	0		42	0	0	1
200 ppm	38	0	1	8	6	12	9	2		0	3	10	14	8	3		38	0	0	0	0	0		32	6	0	0	0	0		38	0	0	0
400 ppm	38	0	1	5	3	6	15	8		0	2	12	17	6	1		38	0	0	0	0	0		28	9	0	0	0	1		37	0	0	1
800 ppm	30	0	13	6	5	2	3	1	*	0	0	1	4	18	7	*	30	0	0	0	0	0		10	20	0	0	0	0	**	29	1	0	0

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

Test of CHI SQUARE

(HCL101)

BAIS3

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
MEASURE. TIME : 1  
SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Occult blood					CHI	Urobilinogen					CHI
		-	±	+	2+	3+		±	+	2+	3+	4+	
Control	43	43	0	0	0	0		42	0	0	1	0	
200 ppm	38	37	0	0	0	1		38	0	0	0	0	
400 ppm	38	34	0	1	0	3		38	0	0	0	0	
800 ppm	30	28	1	0	0	1		30	0	0	0	0	

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

Test of CHI SQUARE

(HCL101)

BAIS3



APPENDIX G 1

GROSS FINDINGS: SUMMARY, RAT: MALE: ALL ANIMALS

( 2-YEAR STUDY )

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 50 (%)	200 ppm 50 (%)	400 ppm 50 (%)	800 ppm 50 (%)
skin/app	nodule		3 ( 6)	2 ( 4)	3 ( 6)	1 ( 2)
subcutis	edema		0 ( 0)	1 ( 2)	1 ( 2)	0 ( 0)
	jaundice		0 ( 0)	1 ( 2)	2 ( 4)	1 ( 2)
	mass		7 ( 14)	15 ( 30)	4 ( 8)	3 ( 6)
lung	red		1 ( 2)	0 ( 0)	1 ( 2)	0 ( 0)
	white zone		3 ( 6)	2 ( 4)	3 ( 6)	2 ( 4)
	red zone		0 ( 0)	1 ( 2)	2 ( 4)	0 ( 0)
	brown zone		0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
	red patch		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	nodule		1 ( 2)	2 ( 4)	2 ( 4)	2 ( 4)
	adhesion		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
lymph node	enlarged		2 ( 4)	0 ( 0)	1 ( 2)	1 ( 2)
spleen	enlarged		2 ( 4)	3 ( 6)	5 ( 10)	3 ( 6)
	white zone		0 ( 0)	2 ( 4)	1 ( 2)	0 ( 0)
	nodule		0 ( 0)	1 ( 2)	0 ( 0)	1 ( 2)
	deformed		1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)
heart	white zone		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
oral cavity	nodule		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	mass		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
salivary gl	nodule		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
forestomach	nodule		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control 50 (%)	200 ppm 50 (%)	400 ppm 50 (%)	800 ppm 50 (%)
forestomach	ulcer		2 ( 4)	1 ( 2)	0 ( 0)	0 ( 0)
gl stomach	red zone		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
liver	enlarged		0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)
	white zone		0 ( 0)	5 ( 10)	8 ( 16)	23 ( 46)
	red zone		1 ( 2)	1 ( 2)	1 ( 2)	2 ( 4)
	nodule		2 ( 4)	3 ( 6)	17 ( 34)	41 ( 82)
	herniation		4 ( 8)	2 ( 4)	4 ( 8)	2 ( 4)
	accentuation of lobular structure		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)
pancreas	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
kidney	white zone		0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)
	nodule		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
	cyst		0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)
	deformed		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
	granular		19 ( 38)	28 ( 56)	20 ( 40)	32 ( 64)
urin bladd	urine:marked retention		0 ( 0)	2 ( 4)	0 ( 0)	1 ( 2)
pituitary	enlarged		5 ( 10)	4 ( 8)	1 ( 2)	0 ( 0)
	red		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	red zone		1 ( 2)	2 ( 4)	1 ( 2)	1 ( 2)
	brown zone		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
	nodule		4 ( 8)	5 ( 10)	0 ( 0)	2 ( 4)
thyroid	enlarged		5 ( 10)	3 ( 6)	6 ( 12)	2 ( 4)

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 50 (%)	200 ppm 50 (%)	400 ppm 50 (%)	800 ppm 50 (%)
thyroid	red zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	black zone		0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
	nodule		1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)
adrenal	enlarged		3 ( 6)	0 ( 0)	4 ( 8)	0 ( 0)
testis	atrophic		2 ( 4)	3 ( 6)	1 ( 2)	4 ( 8)
	nodule		45 ( 90)	43 ( 86)	46 ( 92)	37 ( 74)
epididymis	atrophic		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
brain	enlarged		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	swollen		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	white zone		0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
	hemorrhage		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
	soft		0 ( 0)	1 ( 2)	1 ( 2)	0 ( 0)
eye	white		4 ( 8)	5 ( 10)	2 ( 4)	3 ( 6)
peritoneum	nodule		1 ( 2)	1 ( 2)	1 ( 2)	1 ( 2)
retroperit	mass		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
abdominal c	ascites		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
thoracic ca	pleural fluid		0 ( 0)	2 ( 4)	2 ( 4)	1 ( 2)
other	ear:nodule		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	forelimb:nodule		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	hindlimb:nodule		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
	nose:nodule		0 ( 0)	1 ( 2)	1 ( 2)	0 ( 0)
whole body	anemic		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)

## APPENDIX G 2

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

( 2-YEAR STUDY )

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 8 (%)	200 ppm 12 (%)	400 ppm 10 (%)	800 ppm 13 (%)
skin/app	nodule		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
subcutis	edema		0 ( 0)	1 ( 8)	1 ( 10)	0 ( 0)
	jaundice		0 ( 0)	1 ( 8)	2 ( 20)	1 ( 8)
	mass		2 ( 25)	6 ( 50)	2 ( 20)	2 ( 15)
lung	red		1 ( 13)	0 ( 0)	1 ( 10)	0 ( 0)
	red zone		0 ( 0)	0 ( 0)	1 ( 10)	0 ( 0)
	brown zone		0 ( 0)	0 ( 0)	1 ( 10)	0 ( 0)
	red patch		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)
	nodule		0 ( 0)	1 ( 8)	1 ( 10)	2 ( 15)
lymph node	enlarged		1 ( 13)	0 ( 0)	1 ( 10)	1 ( 8)
spleen	enlarged		2 ( 25)	2 ( 17)	4 ( 40)	2 ( 15)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)
heart	white zone		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)
oral cavity	nodule		1 ( 13)	0 ( 0)	0 ( 0)	0 ( 0)
	mass		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
forestomach	ulcer		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
sl stomach	red zone		1 ( 13)	0 ( 0)	0 ( 0)	0 ( 0)
liver	enlarged		0 ( 0)	0 ( 0)	2 ( 20)	0 ( 0)
	white zone		0 ( 0)	0 ( 0)	1 ( 10)	2 ( 15)
	red zone		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 15)
	nodule		0 ( 0)	0 ( 0)	4 ( 40)	5 ( 38)

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuGrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control 8 (%)	200 ppm 12 (%)	400 ppm 10 (%)	800 ppm 13 (%)
liver	herniation		1 ( 13)	1 ( 8)	0 ( 0)	0 ( 0)
	accentuation of lobular structure		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 15)
kidney	white zone		0 ( 0)	0 ( 0)	2 ( 20)	0 ( 0)
	deformed		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
	granular		0 ( 0)	1 ( 8)	0 ( 0)	2 ( 15)
urin bladd	urine:marked retention		0 ( 0)	1 ( 8)	0 ( 0)	1 ( 8)
pituitary	enlarged		2 ( 25)	1 ( 8)	0 ( 0)	0 ( 0)
	red zone		1 ( 13)	1 ( 8)	0 ( 0)	0 ( 0)
	brown zone		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)
adrenal	enlarged		1 ( 13)	0 ( 0)	2 ( 20)	0 ( 0)
testis	atrophic		0 ( 0)	2 ( 17)	0 ( 0)	2 ( 15)
	nodule		6 ( 75)	8 ( 67)	6 ( 60)	4 ( 31)
brain	enlarged		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)
	swollen		1 ( 13)	0 ( 0)	0 ( 0)	0 ( 0)
	soft		0 ( 0)	1 ( 8)	1 ( 10)	0 ( 0)
eye	white		0 ( 0)	1 ( 8)	0 ( 0)	1 ( 8)
thoracic ca	pleural fluid		0 ( 0)	1 ( 8)	2 ( 20)	1 ( 8)

## APPENDIX G 3

GROSS FINDINGS: SUMMARY, RAT: MALE : SACRIFICED ANIMALS

( 2-YEAR STUDY )



STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (105W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 42 (%)	200 ppm 38 (%)	400 ppm 40 (%)	800 ppm 37 (%)
skin/app	nodule		3 ( 7)	1 ( 3)	3 ( 8)	1 ( 3)
subcutis	mass		5 ( 12)	9 ( 24)	2 ( 5)	1 ( 3)
lung	white zone		3 ( 7)	2 ( 5)	3 ( 8)	2 ( 5)
	red zone		0 ( 0)	1 ( 3)	1 ( 3)	0 ( 0)
	nodule		1 ( 2)	1 ( 3)	1 ( 3)	0 ( 0)
	adhesion		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
lymph node	enlarged		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
spleen	enlarged		0 ( 0)	1 ( 3)	1 ( 3)	1 ( 3)
	white zone		0 ( 0)	2 ( 5)	1 ( 3)	0 ( 0)
	nodule		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
	deformed		1 ( 2)	1 ( 3)	0 ( 0)	0 ( 0)
salivary gl	nodule		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
forestomach	nodule		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
	ulcer		2 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
gl stomach	nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
liver	white zone		0 ( 0)	5 ( 13)	7 ( 18)	21 ( 57)
	red zone		1 ( 2)	1 ( 3)	1 ( 3)	0 ( 0)
	nodule		2 ( 5)	3 ( 8)	13 ( 33)	36 ( 97)
	herniation		3 ( 7)	1 ( 3)	4 ( 10)	2 ( 5)
pancreas	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
kidney	nodule		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
	cyst		0 ( 0)	2 ( 5)	0 ( 0)	0 ( 0)

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (105W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control 42 (%)	200 ppm 38 (%)	400 ppm 40 (%)	800 ppm 37 (%)
kidney	granular		19 ( 45)	27 ( 71)	20 ( 50)	30 ( 81)
urin bladd	urine:marked retention		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
pituitary	enlarged		3 ( 7)	3 ( 8)	1 ( 3)	0 ( 0)
	red		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	red zone		0 ( 0)	1 ( 3)	1 ( 3)	1 ( 3)
	nodule		4 ( 10)	5 ( 13)	0 ( 0)	1 ( 3)
thyroid	enlarged		5 ( 12)	3 ( 8)	6 ( 15)	2 ( 5)
	red zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
	black zone		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	nodule		1 ( 2)	1 ( 3)	0 ( 0)	0 ( 0)
adrenal	enlarged		2 ( 5)	0 ( 0)	2 ( 5)	0 ( 0)
testis	atrophic		2 ( 5)	1 ( 3)	1 ( 3)	2 ( 5)
	nodule		39 ( 93)	35 ( 92)	40 (100)	33 ( 89)
epididymis	atrophic		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
brain	white zone		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	hemorrhage		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
eye	white		4 ( 10)	4 ( 11)	2 ( 5)	2 ( 5)
peritoneum	nodule		1 ( 2)	1 ( 3)	1 ( 3)	1 ( 3)
retroperit	mass		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
abdominal c	ascites		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
thoracic ca	pleural fluid		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
other	ear:nodule		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS (105W)

PAGE : 3

Organ	Findings	Group Name	Control	200 ppm	400 ppm	800 ppm
		NO. of Animals	42 (%)	38 (%)	40 (%)	37 (%)
other	forelimb:nodule		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	hindlimb:nodule		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
	nose:nodule		0 ( 0)	1 ( 3)	1 ( 3)	0 ( 0)
whole body	anemic		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 5)

(HPT080)

BAIS3

## APPENDIX G 4

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 4

Organ	Findings	Group Name NO. of Animals	Control 49 (%)	200 ppm 50 (%)	400 ppm 50 (%)	800 ppm 50 (%)
skin/app	nodule		1 ( 2)	0 ( 0)	0 ( 0)	1 ( 2)
subcutis	edema		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	jaundice		1 ( 2)	1 ( 2)	4 ( 8)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	mass		10 ( 20)	10 ( 20)	0 ( 0)	2 ( 4)
lung	red		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
	white zone		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	red zone		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	1 ( 2)	2 ( 4)	0 ( 0)
lymph node	enlarged		1 ( 2)	0 ( 0)	1 ( 2)	1 ( 2)
thymus	enlarged		0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
	atrophic		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	red		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	red zone		0 ( 0)	0 ( 0)	0 ( 0)	5 ( 10)
spleen	enlarged		4 ( 8)	5 ( 10)	7 ( 14)	4 ( 8)
	black zone		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)
	nodule		0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
heart	white zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	hypertrophy		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
forestomach	ulcer		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
sl stomach	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	ulcer		0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 5

Organ	Findings	Group Name NO. of Animals	Control 49 (%)	200 ppm 50 (%)	400 ppm 50 (%)	800 ppm 50 (%)
gl stomach	erosion		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
stomach	red zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
large intes	nodule		0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
	invagination		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
liver	white zone		1 ( 2)	6 ( 12)	15 ( 30)	10 ( 20)
	red zone		1 ( 2)	1 ( 2)	0 ( 0)	5 ( 10)
	nodule		3 ( 6)	6 ( 12)	14 ( 28)	31 ( 62)
	cyst		0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
	rough		1 ( 2)	1 ( 2)	2 ( 4)	1 ( 2)
	nodular		0 ( 0)	0 ( 0)	1 ( 2)	3 ( 6)
	herniation		5 ( 10)	3 ( 6)	6 ( 12)	3 ( 6)
	accentuation of lobular structure		0 ( 0)	0 ( 0)	0 ( 0)	5 ( 10)
pancreas	nodule		0 ( 0)	1 ( 2)	1 ( 2)	0 ( 0)
kidney	enlarged		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	granular		5 ( 10)	1 ( 2)	0 ( 0)	3 ( 6)
urin bladd	hemorrhage		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
	urine:marked retention		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
pituitary	enlarged		11 ( 22)	8 ( 16)	8 ( 16)	2 ( 4)
	red zone		6 ( 12)	8 ( 16)	5 ( 10)	0 ( 0)
	black zone		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 6

Organ	Findings	Group Name NO. of Animals	Control 49 (%)	200 ppm 50 (%)	400 ppm 50 (%)	800 ppm 50 (%)
pituitary	nodule		7 ( 14)	9 ( 18)	3 ( 6)	2 ( 4)
thyroid	enlarged		2 ( 4)	1 ( 2)	0 ( 0)	1 ( 2)
adrenal	enlarged		1 ( 2)	0 ( 0)	2 ( 4)	1 ( 2)
ovary	enlarged		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	cyst		1 ( 2)	2 ( 4)	3 ( 6)	1 ( 2)
uterus	nodule		1 ( 2)	5 ( 10)	3 ( 6)	0 ( 0)
	cyst		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
prep/cli gl	nodule		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
brain	red zone		0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)
spinal cord	red zone		0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)
eye	turbid		0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
	white		3 ( 6)	3 ( 6)	4 ( 8)	2 ( 4)
	red		0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
Zymbal gl	nodule		0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
peritoneum	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
abdominal c	ascites		0 ( 0)	0 ( 0)	1 ( 2)	2 ( 4)
thoracic ca	hemorrhage		0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
	pleural fluid		0 ( 0)	0 ( 0)	0 ( 0)	6 ( 12)
other	nose:nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
whole body	anemic		0 ( 0)	2 ( 4)	1 ( 2)	0 ( 0)

## APPENDIX G 5

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

( 2-YEAR STUDY )



STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 7 (%)	200 ppm 12 (%)	400 ppm 12 (%)	800 ppm 20 (%)
subcutis	edema		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
	jaundice		1 ( 14)	1 ( 8)	3 ( 25)	0 ( 0)
	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
	mass		3 ( 43)	4 ( 33)	0 ( 0)	0 ( 0)
lung	red		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
	white zone		1 ( 14)	0 ( 0)	0 ( 0)	0 ( 0)
lymph node	enlarged		1 ( 14)	0 ( 0)	0 ( 0)	1 ( 5)
thymus	enlarged		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
	atrophic		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
	red		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
	red zone		0 ( 0)	0 ( 0)	0 ( 0)	5 ( 25)
	enlarged		2 ( 29)	5 ( 42)	5 ( 42)	1 ( 5)
spleen	black zone		0 ( 0)	0 ( 0)	0 ( 0)	2 ( 10)
	hypertrophy		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
forestomach	ulcer		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
stomach	ulcer		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
	erosion		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
large intes	red zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
	nodule		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
liver	invagination		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
	white zone		0 ( 0)	0 ( 0)	0 ( 0)	3 ( 15)
	red zone		0 ( 0)	0 ( 0)	0 ( 0)	5 ( 25)

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 4

Organ	Findings	Group Name NO. of Animals	Control 7 (%)	200 ppm 12 (%)	400 ppm 12 (%)	800 ppm 20 (%)
liver	nodule		0 ( 0)	1 ( 8)	1 ( 8)	2 ( 10)
	rough		1 ( 14)	0 ( 0)	1 ( 8)	1 ( 5)
	nodular		0 ( 0)	0 ( 0)	1 ( 8)	3 ( 15)
	herniation		0 ( 0)	0 ( 0)	2 ( 17)	2 ( 10)
	accentuation of lobular structure		0 ( 0)	0 ( 0)	0 ( 0)	5 ( 25)
pancreas	nodule		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
kidney	enlarged		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
urin bladd	hemorrhage		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
	urine:marked retention		1 ( 14)	0 ( 0)	0 ( 0)	0 ( 0)
pituitary	enlarged		3 ( 43)	4 ( 33)	3 ( 25)	1 ( 5)
	red zone		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
	black zone		1 ( 14)	0 ( 0)	0 ( 0)	0 ( 0)
	nodule		1 ( 14)	2 ( 17)	0 ( 0)	0 ( 0)
adrenal	enlarged		0 ( 0)	0 ( 0)	2 ( 17)	0 ( 0)
ovary	cyst		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
uterus	nodule		1 ( 14)	2 ( 17)	0 ( 0)	0 ( 0)
prop/cli gl	nodule		0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
brain	red zone		0 ( 0)	0 ( 0)	2 ( 17)	0 ( 0)
spinal cord	red zone		0 ( 0)	0 ( 0)	2 ( 17)	0 ( 0)
peritoneum	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)
abdominal c	ascites		0 ( 0)	0 ( 0)	1 ( 8)	2 ( 10)
thoracic ca	hemorrhage		0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 5

Organ	Findings	Group Name	Control	200 ppm	400 ppm	800 ppm
		NO. of Animals	7 (%)	12 (%)	12 (%)	20 (%)
thoracic ca	pleural fluid		0 ( 0)	0 ( 0)	0 ( 0)	6 ( 30)
whole body	anemic		0 ( 0)	2 ( 17)	1 ( 8)	0 ( 0)

(HPT080)

BAIS 3

## APPENDIX G 6

GROSS FINDINGS: SUMMARY, RAT : FEMALE : SACRIFICED ANIMALS

( 2-YEAR STUDY )

STUDY NO. : 0296  
 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 42 (%)	200 ppm 38 (%)	400 ppm 38 (%)	800 ppm 30 (%)
skin/app	nodule		1 ( 2)	0 ( 0)	0 ( 0)	1 ( 3)
subcutis	jaundice		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	mass		7 ( 17)	6 ( 16)	0 ( 0)	2 ( 7)
lung	red zone		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
	nodule		0 ( 0)	1 ( 3)	2 ( 5)	0 ( 0)
lymph node	enlarged		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
spleen	enlarged		2 ( 5)	0 ( 0)	2 ( 5)	3 ( 10)
	nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
heart	white zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
st stomach	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
liver	white zone		1 ( 2)	6 ( 16)	15 ( 39)	7 ( 23)
	red zone		1 ( 2)	1 ( 3)	0 ( 0)	0 ( 0)
	nodule		3 ( 7)	5 ( 13)	13 ( 34)	29 ( 97)
	cyst		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	rough		0 ( 0)	1 ( 3)	1 ( 3)	0 ( 0)
	herniation		5 ( 12)	3 ( 8)	4 ( 11)	1 ( 3)
pancreas	nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
kidney	nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)
	granular		5 ( 12)	1 ( 3)	0 ( 0)	3 ( 10)
urin bladd	nodule		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
pituitary	enlarged		8 ( 19)	4 ( 11)	5 ( 13)	1 ( 3)
	red zone		6 ( 14)	7 ( 18)	5 ( 13)	0 ( 0)

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS (105W)

PAGE : 5

Organ	Findings	Group Name NO. of Animals	Control	200 ppm	400 ppm	800 ppm
			42 (%)	38 (%)	38 (%)	30 (%)
pituitary	nodule		6 ( 14)	7 ( 18)	3 ( 8)	2 ( 7)
thyroid	enlarged		2 ( 5)	1 ( 3)	0 ( 0)	1 ( 3)
adrenal	enlarged		1 ( 2)	0 ( 0)	0 ( 0)	1 ( 3)
ovary	enlarged		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	cyst		1 ( 2)	2 ( 5)	3 ( 8)	0 ( 0)
uterus	nodule		0 ( 0)	3 ( 8)	3 ( 8)	0 ( 0)
	cyst		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)
eye	turbid		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
	white		3 ( 7)	3 ( 8)	4 ( 11)	2 ( 7)
	red		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
Zymal gl	nodule		0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)
other	nose:nodule		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)

(HPT080)

BAIS3

## APPENDIX H 1

ORGAN WEIGHT , ABSOLUTE: SUMMARY, RAT: MALE

( 2-YEAR STUDY )

STUDY NO. : 0296  
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 Weight	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS
Control	42	367± 39	0.102± 0.110	4.493± 1.887	1.343± 0.163	1.563± 0.225	2.798± 0.256
200 ppm	38	343± 26*	0.082± 0.019	3.859± 1.778	1.289± 0.161	1.590± 0.412	3.043± 0.632*
400 ppm	40	326± 24**	0.074± 0.029**	4.742± 1.726	1.198± 0.087**	1.419± 0.148**	2.602± 0.149**
800 ppm	37	279± 20**	0.069± 0.009**	3.433± 1.762*	1.149± 0.093**	1.373± 0.105**	2.704± 0.324

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

Test of Dunnett

(HCL040)

BAIS3



STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE  
UNIT: g

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

PAGE : 2

Group Name	NO. of Animals	SPLEEN		LIVER		BRAIN	
Control	42	0.958±	0.344	11.176±	1.718	1.996±	0.046
200 ppm	38	1.118±	0.348*	13.292±	2.103**	1.979±	0.063
400 ppm	40	1.176±	1.366	12.237±	2.390	1.952±	0.055**
800 ppm	37	1.166±	0.385**	15.774±	3.072**	1.868±	0.045**

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

Test of Dunnett

(HCL040)

BAIS3

## APPENDIX H 2

ORGAN WEIGHT , ABSOLUTE: SUMMARY, RAT: FEMALE

( 2-YEAR STUDY )

STUDY NO. : 0296  
 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	ADRENALS	OVARIES	HEART	LUNGS	KIDNEYS
Control	42	260± 29	0.102± 0.122	0.146± 0.111	0.971± 0.093	1.136± 0.178	1.828± 0.174
200 ppm	38	237± 25*	0.073± 0.008**	0.133± 0.055	0.950± 0.084	1.077± 0.121	1.786± 0.137
400 ppm	38	202± 21**	0.064± 0.007**	0.120± 0.058**	0.899± 0.105**	1.030± 0.115**	1.681± 0.135**
800 ppm	30	184± 12**	0.067± 0.025**	0.084± 0.018**	0.850± 0.107**	1.030± 0.250**	2.734± 5.397

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

Test of Dunnett

(HCL040)

BAIS 3

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE  
UNIT: g

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

PAGE : 4

Group Name	NO. of Animals	SPLEEN		LIVER		BRAIN	
Control	42	0.731±	0.868	7.033±	1.044	1.820±	0.050
200 ppm	38	0.723±	0.318*	7.880±	1.554*	1.814±	0.043
400 ppm	38	1.002±	1.539	7.462±	1.312	1.776±	0.055**
800 ppm	30	0.872±	0.845	9.176±	1.448**	1.711±	0.042**

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

Test of Dunnett

(HCL040)

BAIS3

APPENDIX I 1

ORGAN WEIGHT, RELATIVE: SUMMARY, RAT: MALE

( 2-YEAR STUDY )

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuGrj  
 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	42	367± 39	0.028± 0.031	1.224± 0.528	0.368± 0.047	0.430± 0.076	0.773± 0.126
200 ppm	38	343± 26*	0.024± 0.006	1.120± 0.497	0.378± 0.057	0.469± 0.149	0.892± 0.178**
400 ppm	40	326± 24**	0.023± 0.009	1.451± 0.513	0.370± 0.036	0.439± 0.061	0.802± 0.060
800 ppm	37	279± 20**	0.025± 0.004	1.213± 0.578	0.413± 0.044**	0.494± 0.049**	0.973± 0.143**

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

Test of Dunnett

(HCL042)

BAIS 3

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE  
UNIT: %

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

PAGE : 2

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	42	0.261± 0.091	3.062± 0.484	0.550± 0.064
200 ppm	38	0.327± 0.102**	3.901± 0.694**	0.580± 0.040*
400 ppm	40	0.369± 0.480*	3.766± 0.762**	0.602± 0.041**
800 ppm	37	0.419± 0.143**	5.681± 1.225**	0.671± 0.043**

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

Test of Dunnett

(HCL042)

BAIS3

APPENDIX 12

ORGAN WEIGHT, RELATIVE: SUMMARY, RAT: FEMALE

( 2-YEAR STUDY )



STUDY NO. : 0296  
 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	42	260± 29	0.039± 0.043	0.056± 0.042	0.377± 0.050	0.444± 0.112	0.709± 0.096
200 ppm	38	237± 25*	0.031± 0.006	0.057± 0.026	0.403± 0.034	0.458± 0.062	0.762± 0.104
400 ppm	38	202± 21**	0.032± 0.005	0.059± 0.029	0.451± 0.080**	0.521± 0.120**	0.846± 0.156**
800 ppm	30	184± 12**	0.037± 0.016	0.046± 0.011	0.465± 0.068**	0.565± 0.158**	1.531± 3.169**

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

Test of Dunnett

(HCL042)

BAIS3

STUDY NO. : 0296  
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	42	0.287± 0.362	2.722± 0.461	0.708± 0.086
200 ppm	38	0.305± 0.128**	3.317± 0.478**	0.775± 0.096*
400 ppm	38	0.552± 1.005**	3.740± 0.853**	0.891± 0.110**
800 ppm	30	0.477± 0.473**	5.006± 0.759**	0.936± 0.064**

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

Test of Dunnett

(HCL042)

BAIS 3

APPENDIX J 1

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 1

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Integumentary system/appandage]																		
skin/app			<50>				<50>				<50>				<50>			
	inflammation		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	hyperplasia:epidermis		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
[Respiratory system]																		
nasal cavit			<50>				<50>				<50>				<50>			
	thrombus		0	1	0	0	0	1	0	0	0	0	1	0	0	0	0	0
			( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	mineralization		43	2	0	0	34	16	0	0 **	19	29	0	0 **	23	17	0	0 **
			( 86 )	( 4 )	( 0 )	( 0 )	( 68 )	( 32 )	( 0 )	( 0 )	( 38 )	( 58 )	( 0 )	( 0 )	( 46 )	( 34 )	( 0 )	( 0 )
	fibrosis		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	squamous cell hyperplasia		0	0	0	0	2	0	0	0	0	0	0	0	2	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 2 )	( 0 )	( 0 )
	goblet cell hyperplasia		1	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 2

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

---

[Respiratory system]

nasal cavit

eosinophilic change:olfactory epithelium

<50>

39  
( 78 )

3  
( 6 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

<50>

38  
( 76 )

1  
( 2 )

0  
( 0 )

0  
( 0 )

<50>

29  
( 58 )

4  
( 8 )

0  
( 0 )

0  
( 0 )

<50>

28  
( 56 )

12  
( 24 )

0  
( 0 )

0 \*  
( 0 )

eosinophilic change:respiratory epithelium

15  
( 30 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

18  
( 36 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

9  
( 18 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

19  
( 38 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

inflammation:foreign body

22  
( 44 )

2  
( 4 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

17  
( 34 )

3  
( 6 )

0  
( 0 )

0  
( 0 )

15  
( 30 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

4  
( 8 )

0  
( 0 )

0  
( 0 )

0 \*\*  
( 0 )

inflammation:squamous epithelium

0  
( 0 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

4  
( 8 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

1  
( 2 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

inflammation:respiratory epithelium

0  
( 0 )

0  
( 0 )

0  
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0  
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0  
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1  
( 2 )

0  
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0  
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1  
( 2 )

0  
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0  
( 0 )

0  
( 0 )

erosion:squamous epithelium

1  
( 2 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

0  
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0  
( 0 )

0  
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0  
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0  
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0  
( 0 )

0  
( 0 )

respiratory metaplasia:olfactory epithelium

7  
( 14 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

8  
( 16 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

3  
( 6 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

3  
( 6 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

respiratory metaplasia:gland

46  
( 92 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

45  
( 90 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

45  
( 90 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

43  
( 86 )

0  
( 0 )

0  
( 0 )

0  
( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 3

Organ	Findings	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study				50				50				50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																	
nasal cavit		<50>				<50>				<50>				<50>			
	squamous cell metaplasia:respiratory epithelium	0	0	0	0	1	0	0	0	0	0	0	0	2	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	ulcer:respiratory epithelium	0	1	0	0	1	0	0	0	0	0	1	0	0	0	0	0
		( 0 )	( 2 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	atrophy:olfactory epithelium	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	hyperplasia:respiratory epithelium	1	0	0	0	2	0	0	0	1	0	0	0	0	0	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
nasopharynx		<50>				<50>				<50>				<50>			
	erosion	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
larynx		<50>				<50>				<50>				<50>			
	inflammation	1	0	0	0	6	0	0	0	1	0	0	0	5	0	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 12 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )
trachea		<50>				<50>				<50>				<50>			
	inflammation	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 4

Organ	Findings	Control No. of Animals on Study Grade				200 ppm 50				400 ppm 50				800 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																	
lung		<50>				<50>				<50>				<50>			
	congestion	1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)	1 ( 2)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	5 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	hemorrhage	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	5 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)
	edema	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	deposit of hemosiderin	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	inflammatory infiltration	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)
	osseous metaplasia	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)
	accumulation of foamy cells	9 ( 18)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	10 ( 20)	0 ( 0)	0 ( 0)	0 ( 0)
	bronchiolar-alveolar cell hyperplasia	1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	3 ( 6)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	1 ( 2)	0 ( 0)

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 5

Organ	Findings	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study				No. of Animals on Study				No. of Animals on Study				No. of Animals on Study			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																	
Lung		<50>				<50>				<50>				<50>			
	thickening:pleura	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
[Hematopoietic system]																	
bone marrow		<50>				<50>				<50>				<50>			
	congestion	2	0	0	0	1	0	0	0	1	0	0	0	5	0	0	0
		( 4)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)
	angiectasis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)
	hemorrhage	1	0	0	0	3	0	0	0	1	0	0	0	4	0	0	0
		( 2)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)
	thrombus	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	granulation	2	0	0	0	0	0	0	0	3	0	0	0	5	0	0	0
		( 4)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)
	increased hematopoiesis	8	0	0	0	9	0	0	0	3	0	0	0	6	1	0	0
		( 16)	( 0)	( 0)	( 0)	( 18)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)	( 12)	( 2)	( 0)	( 0)

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



STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 6

Organ	Findings	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study				No. of Animals on Study				No. of Animals on Study				No. of Animals on Study			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]																	
bone marrow		<50>				<50>				<50>				<50>			
	erythropoiesis:increased	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
Lymph node		<50>				<50>				<50>				<50>			
	hemorrhage	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )
	granulation	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	Lymphadenitis	0	0	0	0	2	0	0	0	1	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
thymus		<50>				<50>				<50>				<50>			
	hemorrhage	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
spleen		<50>				<50>				<50>				<49>			
	necrosis:focal	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	vacuolic change	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 7

Organ	Findings	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study				50				50				50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]																	
spleen		<50>				<50>				<50>				<49>			
	deposit of hemosiderin	7	1	0	0	11	1	0	0	6	1	0	0	8	1	0	0
		( 14 )	( 2 )	( 0 )	( 0 )	( 22 )	( 2 )	( 0 )	( 0 )	( 12 )	( 2 )	( 0 )	( 0 )	( 16 )	( 2 )	( 0 )	( 0 )
	inflammatory infiltration	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	fibrosis	3	0	0	0	3	1	2	0	3	1	0	0	1	0	0	0
		( 6 )	( 0 )	( 0 )	( 0 )	( 6 )	( 2 )	( 4 )	( 0 )	( 6 )	( 2 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	extramedullary hematopoiesis	22	6	2	0	19	2	4	0	23	4	2	0	25	4	3	0
		( 44 )	( 12 )	( 4 )	( 0 )	( 38 )	( 4 )	( 8 )	( 0 )	( 46 )	( 8 )	( 4 )	( 0 )	( 51 )	( 8 )	( 6 )	( 0 )
	stromal hyperplasia	1	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 )	( 2 )	( 0 )	( 0 )	( 0 )
	follicular hyperplasia	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )

[Circulatory system]

heart		<50>				<50>				<50>				<50>			
	thrombus	0	0	0	0	0	2	0	0	1	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 8

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	50				50				50				50			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Circulatory system]																		
heart			<50>				<50>				<50>				<50>			
	necrosis:focal		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 2)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	mineralization		0	0	0	0	1	0	0	0	0	0	0	0	5	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)
	inflammatory cell nest		1	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0
			( 2)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)
	myocardial fibrosis		36	0	0	0	40	1	0	0	38	0	0	0	26	0	0	0
			( 72)	( 0)	( 0)	( 0)	( 80)	( 2)	( 0)	( 0)	( 76)	( 0)	( 0)	( 0)	( 52)	( 0)	( 0)	( 0)
[Digestive system]																		
tooth			<50>				<50>				<50>				<50>			
	cyst		0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)
	inflammation		7	1	0	0	2	0	0	0	6	0	0	0	3	0	0	0
			( 14)	( 2)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)	( 12)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)
	dysplasia		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 9

Organ	Findings	Control No. of Animals on Study Grade				200 ppm 50				400 ppm 50				800 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																	
salivary gl		<50>				<50>				<50>				<50>			
	atrophy	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
stomach		<50>				<50>				<50>				<50>			
	basal cell hyperplasia	0	0	0	0	1	0	0	0	0	0	0	0	2	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	erosion:forestomach	1	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 )	( 2 )	( 0 )	( 0 )	( 0 )
	ulcer:forestomach	2	1	0	0	0	1	1	0	0	0	0	0	0	0	0	0
		( 4 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	hyperplasia:forestomach	0	0	0	0	3	0	0	0	0	1	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	erosion:glandular stomach	2	0	0	0	6	0	0	0	2	0	0	0	2	0	0	0
		( 4 )	( 0 )	( 0 )	( 0 )	( 12 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	ulcer:glandular stomach	1	0	0	0	1	1	0	0	1	0	0	0	1	0	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	dilated glands	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 10

Organ	Findings	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study				No. of Animals on Study				No. of Animals on Study				No. of Animals on Study			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																	
small intes	erosion	<50>				<50>				<50>				<50>			
		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
large intes	inflammation	<50>				<50>				<50>				<50>			
		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
liver	herniation	<50>				<50>				<50>				<50>			
		4	0	0	0	2	0	0	0	4	0	0	0	2	0	0	0
		( 8 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	hemorrhage	0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	peliosis-like lesion	2	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	necrosis:central	0	0	1	0	0	5	0	0 *	0	0	0	0	0	2	3	0
		( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 6 )	( 0 )
	necrosis:focal	0	0	0	0	3	0	0	0	6	1	0	0 *	2	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 12 )	( 2 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 11

Organ	Findings	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study				50				50				50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																	
Liver		<50>				<50>				<50>				<50>			
	fatty change	1	0	0	0	5	0	0	0	6	0	0	0	1	0	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 12 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	inflammatory infiltration	0	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	granulation	15	0	0	0	17	1	0	0	18	1	0	0	8	0	0	0
		( 30 )	( 0 )	( 0 )	( 0 )	( 34 )	( 2 )	( 0 )	( 0 )	( 36 )	( 2 )	( 0 )	( 0 )	( 16 )	( 0 )	( 0 )	( 0 )
	organization	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )
	extramedullary hematopoiesis	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	clear cell focus	10	1	0	0	19	2	0	0	21	14	0	0 **	7	26	7	0 **
		( 20 )	( 2 )	( 0 )	( 0 )	( 38 )	( 4 )	( 0 )	( 0 )	( 42 )	( 28 )	( 0 )	( 0 )	( 14 )	( 52 )	( 14 )	( 0 )
	acidophilic cell focus	12	1	0	0	13	1	0	0	24	10	0	0 **	13	26	1	0 **
		( 24 )	( 2 )	( 0 )	( 0 )	( 26 )	( 2 )	( 0 )	( 0 )	( 48 )	( 20 )	( 0 )	( 0 )	( 26 )	( 52 )	( 2 )	( 0 )
	basophilic cell focus	23	1	0	0	21	5	0	0	22	7	0	0	18	24	0	0 **
		( 46 )	( 2 )	( 0 )	( 0 )	( 42 )	( 10 )	( 0 )	( 0 )	( 44 )	( 14 )	( 0 )	( 0 )	( 36 )	( 48 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 12

Organ	Findings	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study				50				50				50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																	
Liver																	
	vacuolated cell focus	<50>				<50>				<50>				<50>			
		6	0	0	0	0	0	0	0 *	6	1	0	0	10	5	1	0 *
		( 12 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 12 )	( 2 )	( 0 )	( 0 )	( 20 )	( 10 )	( 2 )	( 0 )
	mixed cell focus	0	0	0	0	0	0	0	0	0	1	0	0	3	3	0	0 *
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 6 )	( 6 )	( 0 )	( 0 )
	spongiosis hepatis	4	0	0	0	17	4	0	0 **	20	6	0	0 **	21	3	0	0 **
		( 8 )	( 0 )	( 0 )	( 0 )	( 34 )	( 8 )	( 0 )	( 0 )	( 40 )	( 12 )	( 0 )	( 0 )	( 42 )	( 6 )	( 0 )	( 0 )
	bile duct hyperplasia	49	0	0	0	49	0	0	0	47	0	0	0	44	0	0	0
		( 98 )	( 0 )	( 0 )	( 0 )	( 98 )	( 0 )	( 0 )	( 0 )	( 94 )	( 0 )	( 0 )	( 0 )	( 88 )	( 0 )	( 0 )	( 0 )
	bile ductular proliferation	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	cholangiofibrosis	0	0	0	0	0	1	0	0	0	0	0	0	2	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	biliary cyst	1	0	0	0	0	0	0	0	0	1	0	0	1	1	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )
	regenerative hyperplasia	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 13

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																		
pancreas			<50>				<50>				<50>				<50>			
	atrophy		9	2	0	0	4	4	0	0	3	1	0	0	7	0	0	0
			( 18)	( 4)	( 0)	( 0)	( 8)	( 8)	( 0)	( 0)	( 6)	( 2)	( 0)	( 0)	( 14)	( 0)	( 0)	( 0)
	islet cell hyperplasia		2	2	0	0	0	2	0	0	1	0	1	0	1	0	0	0
			( 4)	( 4)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 2)	( 0)	( 2)	( 0)	( 2)	( 0)	( 0)	( 0)
[Urinary system]																		
kidney			<50>				<50>				<50>				<50>			
	infarct		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	cyst		0	0	0	0	1	0	2	0	0	0	0	0	1	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 4)	( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)
	eosinophilic body		15	0	0	0	24	0	0	0	33	1	0	0 **	28	0	0	0 *
			( 30)	( 0)	( 0)	( 0)	( 48)	( 0)	( 0)	( 0)	( 66)	( 2)	( 0)	( 0)	( 56)	( 0)	( 0)	( 0)
	chronic nephropathy		2	27	14	5	0	15	26	7	1	25	20	3	1	9	28	7 **
			( 4)	( 54)	( 28)	( 10)	( 0)	( 30)	( 52)	( 14)	( 2)	( 50)	( 40)	( 6)	( 2)	( 18)	( 56)	( 14)
	hydronephrosis		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

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



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

Organ	Findings	Group Name	Control				200 ppm				400 ppm				800 ppm				
		No. of Animals on Study	50				50				50				50				
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	
[Urinary system]																			
kidney			<50>				<50>				<50>				<50>				
	papillary necrosis		0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	mineralization:papilla		0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	mineralization:pelvis		1	0	0	0	5	0	0	0	2	0	0	0	2	0	0	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	
	mineralization:cortex		0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	urothelial hyperplasia:pelvis		0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
urin bladd			<50>				<50>				<50>				<50>				
	dilatation		0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )
	ulcer		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
[Endocrine system]																			
pituitary			<50>				<50>				<50>				<50>				
	angiectasis		2	2	0	0	0	0	1	0	1	0	0	1	0	0	0	0	0
			( 4 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 2 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

Grade	1 : Slight	2 : Moderate	3 : Marked	4 : Severe
< a >	a : Number of animals examined at the site			
b	b : Number of animals with lesion			

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 15

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				200 ppm 50				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Endocrine system]																		
pituitary			<50>				<50>				<50>				<50>			
	hemorrhage		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	cyst		1	0	0	0	0	0	0	0	7	0	0	0	1	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 14 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	hyperplasia		10	9	1	0	2	6	2	0	6	5	1	0	10	3	3	0
			( 20 )	( 18 )	( 2 )	( 0 )	( 4 )	( 12 )	( 4 )	( 0 )	( 12 )	( 10 )	( 2 )	( 0 )	( 20 )	( 6 )	( 6 )	( 0 )
	Rathke pouch		1	0	0	0	1	0	0	0	2	0	0	0	1	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	focal hypertrophy		0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
thyroid			<50>				<50>				<50>				<50>			
	ultimibranchial body remanet		2	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0
			( 4 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	C-cell hyperplasia		11	4	1	0	9	3	1	0	2	0	3	0 **	11	1	0	0
			( 22 )	( 8 )	( 2 )	( 0 )	( 18 )	( 6 )	( 2 )	( 0 )	( 4 )	( 0 )	( 6 )	( 0 )	( 22 )	( 2 )	( 0 )	( 0 )
	focal follicular cell hyperplasia		1	0	0	0	0	0	0	0	1	0	2	0	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 16

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

---

[Endocrine system]

adrenal		<50>																
	angiectasis	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	peliosis-like lesion	0	0	0	0	0	0	0	0	3	0	0	0	1	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )
	Lymphocytic infiltration	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	osseous metaplasia	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
extramedullary hematopoiesis	0	0	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0	
	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	
hyperplasia:cortical cell	5	0	1	0	6	0	0	0	0	13	0	0	0	8	1	1	0	
	( 10 )	( 0 )	( 2 )	( 0 )	( 12 )	( 0 )	( 0 )	( 0 )	( 0 )	( 26 )	( 0 )	( 0 )	( 0 )	( 16 )	( 2 )	( 2 )	( 0 )	
hyperplasia:medulla	6	1	2	0	4	3	0	0	0	0	3	0	0 *	1	0	1	0	
	( 12 )	( 2 )	( 4 )	( 0 )	( 8 )	( 6 )	( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 2 )	( 0 )	( 2 )	( 0 )	
accessory cortical nodule	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	
	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 17

Organ	Findings	Control No. of Animals on Study Grade				200 ppm 50				400 ppm 50				800 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Endocrine system]																	
adrenal		<50>				<50>				<50>				<50>			
	focal fatty change:cortex	7	1	0	0	5	0	0	0	7	0	1	0	8	1	0	0
		( 14)	( 2)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 14)	( 0)	( 2)	( 0)	( 16)	( 2)	( 0)	( 0)
[Reproductive system]																	
testis		<50>				<50>				<50>				<50>			
	atrophy	4	2	0	0	9	0	0	0	2	0	0	0	7	1	0	0
		( 8)	( 4)	( 0)	( 0)	( 18)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)	( 14)	( 2)	( 0)	( 0)
	mineralization	0	1	0	0	3	0	0	0	2	0	0	0	4	2	0	0
		( 0)	( 2)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)	( 8)	( 4)	( 0)	( 0)
	interstitial cell hyperplasia	7	0	0	0	5	0	0	0	5	0	0	0	11	0	0	0
		( 14)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 22)	( 0)	( 0)	( 0)
prostate		<50>				<50>				<50>				<50>			
	hemorrhage	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	inflammation	20	0	0	0	24	0	0	0	15	0	0	0	14	0	0	0
		( 40)	( 0)	( 0)	( 0)	( 48)	( 0)	( 0)	( 0)	( 30)	( 0)	( 0)	( 0)	( 28)	( 0)	( 0)	( 0)

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

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

b b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0286  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 18

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				200 ppm 50				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Reproductive system]																		
prostate	hyperplasia		<50>				<50>				<50>				<50>			
			7	4	0	0	5	4	0	0	1	1	0	0 *	2	1	0	0
			( 14 )	( 8 )	( 0 )	( 0 )	( 10 )	( 8 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )	( 4 )	( 2 )	( 0 )	( 0 )
mammary gl	duct ectasia		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )
	galactoceles		<50>				<50>				<50>				<50>			
			3	0	0	0	3	0	0	0	1	0	0	0	0	0	0	0
			( 6 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
prep/cli gl	squamous cell hyperplasia		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
[Nervous system]																		
brain	hemorrhage		<50>				<50>				<50>				<50>			
			0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )
	vacuolic change		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 19

Organ	Findings	Control No. of Animals on Study Grade				200 ppm 50				400 ppm 50				800 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Nervous system]																	
spinal cord	hemorrhage	<50>				<50>				<50>				<50>			
		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
[Special sense organs/appendage]																	
eye	cataract	<50>				<50>				<50>				<50>			
		4	0	0	0	4	0	0	0	1	0	0	0	2	1	0	0
		( 8 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 4 )	( 2 )	( 0 )	( 0 )
	retinal atrophy	0	0	4	0	0	3	3	0	0	2	0	0 *	2	0	2	0
		( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 6 )	( 6 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 4 )	( 0 )	( 4 )	( 0 )
	keratitis	2	0	0	0	2	0	0	0	0	0	0	0	2	0	0	0
		( 4 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
Harder gl	degeneration	<50>				<50>				<50>				<50>			
		2	0	0	0	2	0	0	0	1	0	0	0	0	0	0	0
		( 4 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	inflammatory infiltration	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 20

Organ	Findings	Control No. of Animals on Study Grade				200 ppm No. of Animals on Study Grade				400 ppm No. of Animals on Study Grade				800 ppm No. of Animals on Study Grade			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Special sense organs/appendage]																	
Harder gl		<50>				<50>				<50>				<50>			
	Lymphocytic infiltration	0	0	0	0	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 )
		<50>				<50>				<50>				<50>			
	granulation	0	1	0	0	0	0	0	0	1	0	0	0	2	0	0	0
		( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
nasolacr d		<50>				<50>				<50>				<50>			
	inflammation	0	0	0	0	1	0	0	0	3	0	0	0	4	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )
[Musculoskeletal system]																	
muscle		<50>				<50>				<50>				<50>			
	mineralization	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
bone		<50>				<50>				<50>				<50>			
	fracture	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
		<50>				<50>				<50>				<50>			
	osteodystrophy	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 21

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				200 ppm 50				400 ppm 50				800 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

[Musculoskeletal system]

bone	osteosclerosis	<50>				<50>				<50>				<50>			
		0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

[Body cavities]

peritoneum	peritonitis	<50>				<50>				<50>				<50>			
		0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

(HPT150)

BAIS3



APPENDIX J 2

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 1

Organ	Findings	Control No. of Animals on Study 8 Grade				200 ppm 12				400 ppm 10				800 ppm 13			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Integumentary system/appandage]																	
skin/app		< 8>				<12>				<10>				<13>			
	inflammation	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
[Respiratory system]																	
nasal cavit		< 8>				<12>				<10>				<13>			
	thrombus	0	1	0	0	0	1	0	0	0	1	0	0	0	0	0	0
		( 0 )	( 13 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	mineralization	8	0	0	0	8	4	0	0	3	5	0	0 *	7	2	0	0
		(100)	( 0 )	( 0 )	( 0 )	( 67 )	( 33 )	( 0 )	( 0 )	( 30 )	( 50 )	( 0 )	( 0 )	( 54 )	( 15 )	( 0 )	( 0 )
	eosinophilic change:olfactory epithelium	4	0	0	0	7	0	0	0	3	1	0	0	4	2	0	0
		( 50 )	( 0 )	( 0 )	( 0 )	( 58 )	( 0 )	( 0 )	( 0 )	( 30 )	( 10 )	( 0 )	( 0 )	( 31 )	( 15 )	( 0 )	( 0 )
	eosinophilic change:respiratory epithelium	2	0	0	0	2	0	0	0	1	0	0	0	1	0	0	0
		( 25 )	( 0 )	( 0 )	( 0 )	( 17 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )
	inflammation:foreign body	4	0	0	0	2	0	0	0	2	0	0	0	1	0	0	0
		( 50 )	( 0 )	( 0 )	( 0 )	( 17 )	( 0 )	( 0 )	( 0 )	( 20 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )
	inflammation:squamous epithelium	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 2

Organ	Findings	Control No. of Animals on Study 8 Grade				200 ppm 12				400 ppm 10				800 ppm 13			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																	
nasal cavit		< 8>				<12>				<10>				<13>			
	erosion:squamous epithelium	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 13)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	respiratory metaplasia:olfactory epithelium	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)
	respiratory metaplasia:gland	7	0	0	0	11	0	0	0	7	0	0	0	9	0	0	0
		( 88)	( 0)	( 0)	( 0)	( 92)	( 0)	( 0)	( 0)	( 70)	( 0)	( 0)	( 0)	( 69)	( 0)	( 0)	( 0)
	ulcer:respiratory epithelium	0	1	0	0	1	0	0	0	0	0	1	0	0	0	0	0
		( 0)	( 13)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 0)	( 0)
	hyperplasia:respiratory epithelium	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
larynx		< 8>				<12>				<10>				<13>			
	inflammation	0	0	0	0	2	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)
lung		< 8>				<12>				<10>				<13>			
	congestion	1	1	0	0	0	3	0	0	0	5	0	0	0	0	0	0
		( 13)	( 13)	( 0)	( 0)	( 0)	( 25)	( 0)	( 0)	( 0)	( 50)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 3

Organ	Findings	Control No. of Animals on Study Grade				200 ppm 12				400 ppm 10				800 ppm 13			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																	
Lung		< 8>				<12>				<10>				<13>			
	hemorrhage	1 ( 13)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 20)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)
	edema	2 ( 25)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 20)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	deposit of hemosiderin	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	accumulation of foamy cells	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 25)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
[Hematopoietic system]																	
bone marrow		< 8>				<12>				<10>				<13>			
	angiectasis	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)
	hemorrhage	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 15)	0 ( 0)	0 ( 0)	0 ( 0)
	thrombus	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)

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

STUDY NO. : 0296  
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	Control No. of Animals on Study 8				200 ppm 12				400 ppm 10				800 ppm 13			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]																	
bone marrow		< 8 >				< 12 >				< 10 >				< 13 >			
	increased hematopoiesis	2 ( 25 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	4 ( 33 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 20 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	3 ( 23 )	1 ( 8 )	0 ( 0 )	0 ( 0 )
	erythropoiesis: increased	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
lymph node		< 8 >				< 12 >				< 10 >				< 13 >			
	hemorrhage	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 8 )	0 ( 0 )	0 ( 0 )
	lymphadenitis	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 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
thymus		< 8 >				< 12 >				< 10 >				< 13 >			
	hemorrhage	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
spleen		< 8 >				< 12 >				< 10 >				< 12 >			
	deposit of hemosiderin	1 ( 13 )	1 ( 13 )	0 ( 0 )	0 ( 0 )	5 ( 42 )	1 ( 8 )	0 ( 0 )	0 ( 0 )	3 ( 30 )	1 ( 10 )	0 ( 0 )	0 ( 0 )	3 ( 25 )	1 ( 8 )	0 ( 0 )	0 ( 0 )
	fibrosis	1 ( 13 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 5

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	8				12				10				13			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]																		
spleen			< 8>				<12>				<10>				<12>			
	extramedullary hematopoiesis		1	1	0	0	0	1	4	0	1	0	1	0	0	2	2	0
			( 13)	( 13)	( 0)	( 0)	( 0)	( 8)	( 33)	( 0)	( 10)	( 0)	( 10)	( 0)	( 0)	( 17)	( 17)	( 0)
	stromal hyperplasia		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)
[Circulatory system]																		
heart			< 8>				<12>				<10>				<13>			
	thrombus		0	0	0	0	0	2	0	0	1	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 17)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	necrosis:focal		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 13)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	mineralization		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	inflammatory cell nest		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 13)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	myocardial fibrosis		4	0	0	0	8	0	0	0	6	0	0	0	5	0	0	0
			( 50)	( 0)	( 0)	( 0)	( 67)	( 0)	( 0)	( 0)	( 60)	( 0)	( 0)	( 0)	( 38)	( 0)	( 0)	( 0)

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 6

Organ	Findings	Control No. of Animals on Study Grade				200 ppm 12				400 ppm 10				800 ppm 13			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																	
tooth	inflammation	< 8>				<12>				<10>				<13>			
		1	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0
		( 13)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)
salivary gl	atrophy	< 8>				<12>				<10>				<13>			
		0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0)	( 13)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
stomach	basal cell hyperplasia	< 8>				<12>				<10>				<13>			
		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)	( 15)	( 0)	( 0)	( 0)
	erosion:forestomach	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 13)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)
	ulcer:forestomach	1	1	0	0	0	1	1	0	0	0	0	0	0	0	0	0
		( 13)	( 13)	( 0)	( 0)	( 0)	( 8)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	hyperplasia:forestomach	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	erosion:glandular stomach	2	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
		( 25)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 15)	( 0)	( 0)	( 0)

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

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

b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 7

Organ	Findings	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	8				12				10				13			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

[Digestive system]																		
stomach	ulcer:glandular stomach		< 8>				<12>				<10>				<13>			
		1	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0
			( 13)	( 0)	( 0)	( 0)	( 8)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
small intes	erosion		< 8>				<12>				<10>				<13>			
		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
large intes	inflammation		< 8>				<12>				<10>				<13>			
		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
liver	herniation		< 8>				<12>				<10>				<13>			
		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
			( 13)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	peliosis-like lesion		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)
	necrosis:central		0	0	1	0	0	5	0	0	0	0	0	0	0	1	3	0
			( 0)	( 0)	( 13)	( 0)	( 0)	( 42)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 23)	( 0)
	necrosis:focal		0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 10)	( 10)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

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



STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 8

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	8				12				10				13			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																		
liver			< 8>				<12>				<10>				<13>			
	granulation		1	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
			( 13)	( 0)	( 0)	( 0)	( 17)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	clear cell focus		0	0	0	0	2	0	0	0	2	1	0	0	3	1	0	0
			( 0)	( 0)	( 0)	( 0)	( 17)	( 0)	( 0)	( 0)	( 20)	( 10)	( 0)	( 0)	( 23)	( 8)	( 0)	( 0)
	acidophilic cell focus		0	0	0	0	1	0	0	0	4	1	0	0	4	0	1	0
			( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 40)	( 10)	( 0)	( 0)	( 31)	( 0)	( 8)	( 0)
	basophilic cell focus		3	0	0	0	2	0	0	0	2	0	0	0	2	3	0	0
			( 38)	( 0)	( 0)	( 0)	( 17)	( 0)	( 0)	( 0)	( 20)	( 0)	( 0)	( 0)	( 15)	( 23)	( 0)	( 0)
	mixed cell focus		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)
	spongiosis hepatis		1	0	0	0	3	0	0	0	3	1	0	0	3	0	0	0
			( 13)	( 0)	( 0)	( 0)	( 25)	( 0)	( 0)	( 0)	( 30)	( 10)	( 0)	( 0)	( 23)	( 0)	( 0)	( 0)
	bile duct hyperplasia		7	0	0	0	11	0	0	0	8	0	0	0	7	0	0	0
			( 88)	( 0)	( 0)	( 0)	( 92)	( 0)	( 0)	( 0)	( 80)	( 0)	( 0)	( 0)	( 54)	( 0)	( 0)	( 0)
	regenerative hyperplasia		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 9

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	8				12				10				13			
Grade			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>																		
[Digestive system]																		
pancreas			< 8>				<12>				<10>				<13>			
	atrophy		2	1	0	0	0	1	0	0	1	0	0	0	1	0	0	0
			( 25)	( 13)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)
 [Urinary system]																		
kidney			< 8>				<12>				<10>				<13>			
	infarct		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	cyst		0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	eosinophilic body		1	0	0	0	4	0	0	0	2	1	0	0	2	0	0	0
			( 13)	( 0)	( 0)	( 0)	( 33)	( 0)	( 0)	( 0)	( 20)	( 10)	( 0)	( 0)	( 15)	( 0)	( 0)	( 0)
	chronic nephropathy		1	4	1	0	0	6	4	0	1	8	0	0	1	4	3	0
			( 13)	( 50)	( 13)	( 0)	( 0)	( 50)	( 33)	( 0)	( 10)	( 80)	( 0)	( 0)	( 8)	( 31)	( 23)	( 0)
	hydronephrosis		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	papillary necrosis		0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 10

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	8				12				10				13			
Grade			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Urinary system]																		
kidney			< 8>				<12>				<10>				<13>			
	mineralization:pelvis		0	0	0	0	2	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 )
	mineralization:cortex		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	urothelial hyperplasia:pelvis		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
urin bladd			< 8>				<12>				<10>				<13>			
	dilatation		0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )
	ulcer		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
[Endocrine system]																		
pituitary			< 8>				<12>				<10>				<13>			
	angiectasis		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 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )

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

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

b b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 11

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	8				12				10				13			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Endocrine system]																		
pituitary			< 8>				<12>				<10>				<13>			
	hemorrhage		1 ( 13)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	cyst		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	hyperplasia		1 ( 13)	1 ( 13)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)	1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)	1 ( 8)	0 ( 0)
thyroid			< 8>				<12>				<10>				<13>			
	ultimibranchial body remanet		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 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)
	C-cell hyperplasia		1 ( 13)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 17)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	focal follicular cell hyperplasia		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
adrenal			< 8>				<12>				<10>				<13>			
	extramedullary hematopoiesis		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 12

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	8				12				10				13			
Organ_____	Findings_____	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Endocrine system]																		
adrenal			< 8>				<12>				<10>				<13>			
	hyperplasia:cortical cell		1	0	0	0	0	0	0	0	1	0	0	0	2	0	0	0
			( 13)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 15)	( 0)	( 0)	( 0)
	hyperplasia:medulla		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 13)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	focal fatty change:cortex		0	0	0	0	0	0	0	0	0	0	1	0	2	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 15)	( 0)	( 0)	( 0)
[Reproductive system]																		
testis			< 8>				<12>				<10>				<13>			
	atrophy		1	0	0	0	2	0	0	0	0	0	0	0	3	0	0	0
			( 13)	( 0)	( 0)	( 0)	( 17)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 23)	( 0)	( 0)	( 0)
	mineralization		0	0	0	0	0	0	0	0	1	0	0	0	3	1	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 23)	( 8)	( 0)	( 0)
	interstitial cell hyperplasia		3	0	0	0	2	0	0	0	3	0	0	0	5	0	0	0
			( 38)	( 0)	( 0)	( 0)	( 17)	( 0)	( 0)	( 0)	( 30)	( 0)	( 0)	( 0)	( 38)	( 0)	( 0)	( 0)
prostate			< 8>				<12>				<10>				<13>			
	hemorrhage		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

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

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

b b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 13

Organ	Findings	Group Name No. of Animals on Study Grade	Control 8				200 ppm 12				400 ppm 10				800 ppm 13			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Reproductive system]																		
prostate	inflammation		< 8>				<12>				<10>				<13>			
			2	0	0	0	3	0	0	0	3	0	0	0	2	0	0	0
			( 25 )	( 0 )	( 0 )	( 0 )	( 25 )	( 0 )	( 0 )	( 0 )	( 30 )	( 0 )	( 0 )	( 0 )	( 15 )	( 0 )	( 0 )	( 0 )
	hyperplasia		< 8>				<12>				<10>				<13>			
			1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 13 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
mammary gl	galactoceles		< 8>				<12>				<10>				<13>			
			0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
[Nervous system]																		
brain	hemorrhage		< 8>				<12>				<10>				<13>			
			0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )
spinal cord	hemorrhage		< 8>				<12>				<10>				<13>			
			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 )	( 8 )	( 0 )	( 0 )	( 0 )
[Special sense organs/appendage]																		
eye	cataract		< 8>				<12>				<10>				<13>			
			0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 14

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	8				12				10				13			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Special sense organs/appendage]																		
eye	retinal atrophy		< 8>				<12>				<10>				<13>			
		0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )
	keratitis		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )
Harder gl	degeneration		< 8>				<12>				<10>				<13>			
		0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	inflammatory infiltration		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
nasolacr d	inflammation		< 8>				<12>				<10>				<13>			
		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 )	( 8 )	( 0 )	( 0 )	( 0 )
[Musculoskeletal system]																		
muscle	mineralization		< 8>				<12>				<10>				<13>			
		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

APPENDIX J 3  
HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY,  
RAT: MALE: SACRIFICED ANIMALS  
( 2-YEAR STUDY )



STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 1

Organ	Findings	Control No. of Animals on Study 42 Grade				200 ppm 38				400 ppm 40				800 ppm 37			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Integumentary system/appandage]																	
skin/app		<42>				<38>				<40>				<37>			
	hyperplasia:epidermis	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
[Respiratory system]																	
nasal cavit		<42>				<38>				<40>				<37>			
	mineralization	35	2	0	0	26	12	0	0 **	16	24	0	0 **	16	15	0	0 **
		( 83 )	( 5 )	( 0 )	( 0 )	( 68 )	( 32 )	( 0 )	( 0 )	( 40 )	( 60 )	( 0 )	( 0 )	( 43 )	( 41 )	( 0 )	( 0 )
	fibrosis	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	squamous cell hyperplasia	0	0	0	0	2	0	0	0	0	0	0	0	2	1	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 5 )	( 3 )	( 0 )	( 0 )
	goblet cell hyperplasia	1	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	eosinophilic change:olfactory epithelium	35	3	0	0	31	1	0	0	26	3	0	0	24	10	0	0
		( 83 )	( 7 )	( 0 )	( 0 )	( 82 )	( 3 )	( 0 )	( 0 )	( 65 )	( 8 )	( 0 )	( 0 )	( 65 )	( 27 )	( 0 )	( 0 )
	eosinophilic change:respiratory epithelium	13	0	0	0	16	0	0	0	8	0	0	0	18	0	0	0
		( 31 )	( 0 )	( 0 )	( 0 )	( 42 )	( 0 )	( 0 )	( 0 )	( 20 )	( 0 )	( 0 )	( 0 )	( 49 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 2

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	42				38				40				37			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

---

[Respiratory system]

nasal cavit

inflammation:foreign body

18

( 43)

2

( 5)

0

( 0)

0

( 0)

15

( 39)

3

( 8)

0

( 0)

0

( 0)

13

( 33)

0

( 0)

0

( 0)

0

( 0)

3

( 8)

0

( 0)

0

( 0)

0

( 0)

\*\*

inflammation:squamous epithelium

0

( 0)

0

( 0)

0

( 0)

0

( 0)

3

( 8)

0

( 0)

0

( 0)

0

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1

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0

( 0)

inflammation:respiratory epithelium

0

( 0)

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0

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1

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0

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0

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0

( 0)

0

( 0)

respiratory metaplasia:olfactory epithelium

7

( 17)

0

( 0)

0

( 0)

0

( 0)

8

( 21)

0

( 0)

0

( 0)

0

( 0)

3

( 8)

0

( 0)

0

( 0)

0

( 0)

2

( 5)

0

( 0)

0

( 0)

0

( 0)

respiratory metaplasia:gland

39

( 93)

0

( 0)

0

( 0)

0

( 0)

34

( 89)

0

( 0)

0

( 0)

0

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38

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0

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0

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34

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0

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0

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0

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squamous cell metaplasia:respiratory epithelium

0

( 0)

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0

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1

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0

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atrophy:olfactory epithelium

0

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hyperplasia:respiratory epithelium

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 3

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	42				38				40				37			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

---

[Respiratory system]																					
nasopharynx	erosion	<42>	0	0	0	0	<38>	1	0	0	0	<40>	0	0	0	0	<37>	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )		( 3 )	( 0 )	( 0 )	( 0 )		( 0 )	( 0 )	( 0 )	( 0 )		( 0 )	( 0 )	( 0 )	( 0 )
larynx	inflammation	<42>	1	0	0	0	<38>	4	0	0	0	<40>	1	0	0	0	<37>	5	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )		( 11 )	( 0 )	( 0 )	( 0 )		( 3 )	( 0 )	( 0 )	( 0 )		( 14 )	( 0 )	( 0 )	( 0 )
trachea	inflammation	<42>	0	0	0	0	<38>	0	0	0	0	<40>	0	0	0	0	<37>	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )		( 0 )	( 0 )	( 0 )	( 0 )		( 0 )	( 0 )	( 0 )	( 0 )		( 3 )	( 0 )	( 0 )	( 0 )
lung	congestion	<42>	0	0	0	0	<38>	1	0	0	0	<40>	0	0	0	0	<37>	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )		( 3 )	( 0 )	( 0 )	( 0 )		( 0 )	( 0 )	( 0 )	( 0 )		( 0 )	( 0 )	( 0 )	( 0 )
	hemorrhage		1	0	0	0		1	0	0	0		3	0	0	0		2	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )		( 3 )	( 0 )	( 0 )	( 0 )		( 8 )	( 0 )	( 0 )	( 0 )		( 5 )	( 0 )	( 0 )	( 0 )
	edema		1	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )		( 0 )	( 0 )	( 0 )	( 0 )		( 0 )	( 0 )	( 0 )	( 0 )		( 0 )	( 0 )	( 0 )	( 0 )
	inflammatory infiltration		0	0	0	0		0	0	0	0		1	0	0	0		2	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )		( 0 )	( 0 )	( 0 )	( 0 )		( 3 )	( 0 )	( 0 )	( 0 )		( 5 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 4

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	42				38				40				37			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

---

[Respiratory system]

lung

osseous metaplasia

<42>

3

0

0

0

( 7 )

( 0 )

( 0 )

( 0 )

<38>

3

0

0

0

( 8 )

( 0 )

( 0 )

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<40>

1

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( 0 )

( 0 )

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accumulation of foamy cells

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( 0 )

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( 0 )

10

0

0

0

( 27 )

( 0 )

( 0 )

( 0 )

bronchiolar-alveolar cell hyperplasia

1

1

0

0

( 2 )

( 2 )

( 0 )

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( 0 )

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3

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( 3 )

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thickening:pleura

1

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( 2 )

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( 0 )

( 0 )

( 0 )

( 0 )

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0

0

0

( 0 )

( 0 )

( 0 )

( 0 )

[Hematopoietic system]

bone marrow

congestion

<42>

2

0

0

0

( 5 )

( 0 )

( 0 )

( 0 )

<38>

1

0

0

0

( 3 )

( 0 )

( 0 )

( 0 )

<40>

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0

( 3 )

( 0 )

( 0 )

( 0 )

<37>

5

0

0

0

( 14 )

( 0 )

( 0 )

( 0 )

hemorrhage

1

0

0

0

( 2 )

( 0 )

( 0 )

( 0 )

3

0

0

0

( 8 )

( 0 )

( 0 )

( 0 )

1

0

0

0

( 3 )

( 0 )

( 0 )

( 0 )

2

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0

0

( 5 )

( 0 )

( 0 )

( 0 )

thrombus

0

0

0

0

( 0 )

( 0 )

( 0 )

( 0 )

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( 0 )

( 0 )

( 0 )

( 0 )

0

1

0

0

( 0 )

( 3 )

( 0 )

( 0 )

0

0

0

0

( 0 )

( 0 )

( 0 )

( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 5

Organ	Findings	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	42				38				40				37			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]																		
bone marrow			<42>				<38>				<40>				<37>			
	granulation		2 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	5 (14)	0 ( 0)	0 ( 0)	0 ( 0)
	increased hematopoiesis		6 (14)	0 ( 0)	0 ( 0)	0 ( 0)	5 (13)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)
Lymph node			<42>				<38>				<40>				<37>			
	granulation		2 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	Lymphadenitis		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
spleen			<42>				<38>				<40>				<37>			
	necrosis:focal		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	vacuolic change		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	deposit of hemosiderin		6 (14)	0 ( 0)	0 ( 0)	0 ( 0)	6 (16)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	5 (14)	0 ( 0)	0 ( 0)	0 ( 0)

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 6

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	42				38				40				37			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]																		
spleen			<42>				<38>				<40>				<37>			
	inflammatory infiltration		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	fibrosis		2	0	0	0	3	1	2	0	3	1	0	0	1	0	0	0
			( 5 )	( 0 )	( 0 )	( 0 )	( 8 )	( 3 )	( 5 )	( 0 )	( 8 )	( 3 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )
	extramedullary hematopoiesis		21	5	2	0	19	1	0	0	22	4	1	0	25	2	1	0
			( 50 )	( 12 )	( 5 )	( 0 )	( 50 )	( 3 )	( 0 )	( 0 )	( 55 )	( 10 )	( 3 )	( 0 )	( 68 )	( 5 )	( 3 )	( 0 )
	stromal hyperplasia		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	follicular hyperplasia		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )
[Circulatory system]																		
heart			<42>				<38>				<40>				<37>			
	mineralization		0	0	0	0	0	0	0	0	0	0	0	0	5	0	0	0 *
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 14 )	( 0 )	( 0 )	( 0 )
	inflammatory cell nest		0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 7

Organ	Findings	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	42				38				40				37			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Circulatory system]																		
heart			<42>				<38>				<40>				<37>			
	myocardial fibrosis		32	0	0	0	32	1	0	0	32	0	0	0	21	0	0	0
			( 76)	( 0)	( 0)	( 0)	( 84)	( 3)	( 0)	( 0)	( 80)	( 0)	( 0)	( 0)	( 57)	( 0)	( 0)	( 0)
[Digestive system]																		
tooth			<42>				<38>				<40>				<37>			
	cyst		0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)
	inflammation		6	1	0	0	1	0	0	0	6	0	0	0	2	0	0	0
			( 14)	( 2)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)	( 15)	( 0)	( 0)	( 0)	( 5)	( 0)	( 0)	( 0)
	dysplasia		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
stomach			<42>				<38>				<40>				<37>			
	basal cell hyperplasia		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	ulcer:forestomach		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 8

Organ	Findings	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	42				38				40				37			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																		
stomach			<42>				<38>				<40>				<37>			
	hyperplasia:forestomach		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 5 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	erosion:glandular stomach		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	6 ( 16 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 5 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	ulcer:glandular stomach		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	dilated glands		1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
liver			<42>				<38>				<40>				<37>			
	herniation		3 ( 7 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	4 ( 10 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 5 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	hemorrhage		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	peliosis-like lesion		2 ( 5 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	necrosis:central		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )

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



STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 9

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	42				38				40				37			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																		
liver			<42>				<38>				<40>				<37>			
	necrosis:focal		0	0	0	0	3	0	0	0	5	0	0	0	2	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )
	fatty change		1	0	0	0	5	0	0	0	6	0	0	0	1	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )	( 15 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )
	inflammatory infiltration		0	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )
	granulation		14	0	0	0	15	1	0	0	18	1	0	0	8	0	0	0
			( 33 )	( 0 )	( 0 )	( 0 )	( 39 )	( 3 )	( 0 )	( 0 )	( 45 )	( 3 )	( 0 )	( 0 )	( 22 )	( 0 )	( 0 )	( 0 )
	organization		0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )
	extramedullary hematopoiesis		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )
	clear cell focus		10	1	0	0	17	2	0	0	19	13	0	0 **	4	25	7	0 **
			( 24 )	( 2 )	( 0 )	( 0 )	( 45 )	( 5 )	( 0 )	( 0 )	( 48 )	( 33 )	( 0 )	( 0 )	( 11 )	( 68 )	( 19 )	( 0 )
	acidophilic cell focus		12	1	0	0	12	1	0	0	20	9	0	0 **	9	26	0	0 **
			( 29 )	( 2 )	( 0 )	( 0 )	( 32 )	( 3 )	( 0 )	( 0 )	( 50 )	( 23 )	( 0 )	( 0 )	( 24 )	( 70 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 10

Organ	Findings	Group Name No. of Animals on Study Grade				Control 42				200 ppm 38				400 ppm 40				800 ppm 37			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4				
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)				
[Digestive system]																					
Liver		<42>				<38>				<40>				<37>							
	basophilic cell focus	20 ( 48)	1 ( 2)	0 ( 0)	0 ( 0)	19 ( 50)	5 ( 13)	0 ( 0)	0 ( 0)	20 ( 50)	7 ( 18)	0 ( 0)	0 * ( 0)	16 ( 43)	21 ( 57)	0 ( 0)	0 ** ( 0)				
	vacuolated cell focus	6 ( 14)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 * ( 0)	6 ( 15)	1 ( 3)	0 ( 0)	0 ( 0)	10 ( 27)	5 ( 14)	1 ( 3)	0 * ( 0)				
	mixed cell focus	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	2 ( 5)	3 ( 8)	0 ( 0)	0 * ( 0)				
	spongiosis hepatitis	3 ( 7)	0 ( 0)	0 ( 0)	0 ( 0)	14 ( 37)	4 ( 11)	0 ( 0)	0 ** ( 0)	17 ( 43)	5 ( 13)	0 ( 0)	0 ** ( 0)	18 ( 49)	3 ( 8)	0 ( 0)	0 ** ( 0)				
	bile duct hyperplasia	42 (100)	0 ( 0)	0 ( 0)	0 ( 0)	38 (100)	0 ( 0)	0 ( 0)	0 ( 0)	39 ( 98)	0 ( 0)	0 ( 0)	0 ( 0)	37 (100)	0 ( 0)	0 ( 0)	0 ( 0)				
	bile ductular proliferation	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)				
	cholangiofibrosis	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)				
biliary cyst	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	1 ( 3)	1 ( 3)	0 ( 0)	0 ( 0)					

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 11

Organ	Findings	Control No. of Animals on Study Grade				200 ppm 38				400 ppm 40				800 ppm 37			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																	
pancreas		<42>				<38>				<40>				<37>			
	atrophy	7 ( 17)	1 ( 2)	0 ( 0)	0 ( 0)	4 ( 11)	3 ( 8)	0 ( 0)	0 ( 0)	2 ( 5)	1 ( 3)	0 ( 0)	0 ( 0)	6 ( 16)	0 ( 0)	0 ( 0)	0 ( 0)
	islet cell hyperplasia	2 ( 5)	2 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 5)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	1 ( 3)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
[Urinary system]																	
kidney		<42>				<38>				<40>				<37>			
	cyst	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	eosinophilic body	14 ( 33)	0 ( 0)	0 ( 0)	0 ( 0)	20 ( 53)	0 ( 0)	0 ( 0)	0 ( 0)	31 ( 78)	0 ( 0)	0 ( 0)	0 ( 0)	26 ( 70)	0 ( 0)	0 ( 0)	0 ( 0)
	chronic nephropathy	1 ( 2)	23 ( 55)	13 ( 31)	5 ( 12)	0 ( 0)	9 ( 24)	22 ( 58)	7 ( 18)	0 ( 0)	17 ( 43)	20 ( 50)	3 ( 8)	0 ( 0)	5 ( 14)	25 ( 68)	7 ( 19)
	mineralization:papilla	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	mineralization:pelvis	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 12

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	42				38				40				37			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Urinary system]																		
kidney	mineralization:cortex		<42>				<38>				<40>				<37>			
		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	urothelial hyperplasia:polvis		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )
urin bladd	dilatation		<42>				<38>				<40>				<37>			
		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
[Endocrine system]																		
pituitary	angiectasis		<42>				<38>				<40>				<37>			
		2	2	0	0	0	0	1	0	1	0	1	0	0	0	0	0	0
			( 5 )	( 5 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	cyst		1	0	0	0	0	0	0	0	6	0	0	0	1	0	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 15 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )
	hyperplasia		9	8	1	0	2	5	2	0	5	5	1	0	10	2	2	0
		( 21 )	( 19 )	( 2 )	( 0 )	( 5 )	( 13 )	( 5 )	( 0 )	( 13 )	( 13 )	( 3 )	( 0 )	( 27 )	( 5 )	( 5 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 13

Organ	Findings	Control No. of Animals on Study Grade				200 ppm 38				400 ppm 40				800 ppm 37			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Endocrine system]																	
pituitary		<42>				<38>				<40>				<37>			
	Rathke pouch	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 5 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	focal hypertrophy	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
thyroid		<42>				<38>				<40>				<37>			
	ultimibranhial body remanet	2 ( 5 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	C-cell hyperplasia	10 ( 24 )	4 ( 10 )	1 ( 2 )	0 ( 0 )	7 ( 18 )	3 ( 8 )	1 ( 3 )	0 ( 0 )	2 ( 5 )	0 ( 0 )	3 ( 8 )	0 * ( 0 )	11 ( 30 )	1 ( 3 )	0 ( 0 )	0 ( 0 )
	focal follicular cell hyperplasia	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
adrenal		<42>				<38>				<40>				<37>			
	angiectasis	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	peliosis-like lesion	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	3 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 14

Organ	Findings	Group Name No. of Animals on Study Control Grade				200 ppm 38				400 ppm 40				800 ppm 37			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Endocrine system]																	
adrenal		<42>				<38>				<40>				<37>			
	lymphocytic infiltration	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	osseous metaplasia	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	extramedullary hematopoiesis	0	0	0	0	0	0	0	0	4	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	hyperplasia:cortical cell	4	0	1	0	6	0	0	0	12	0	0	0 *	6	1	1	0
		( 10 )	( 0 )	( 2 )	( 0 )	( 16 )	( 0 )	( 0 )	( 0 )	( 30 )	( 0 )	( 0 )	( 0 )	( 16 )	( 3 )	( 3 )	( 0 )
	hyperplasia:medulla	5	1	2	0	3	3	0	0	0	3	0	0 *	1	0	1	0
		( 12 )	( 2 )	( 5 )	( 0 )	( 8 )	( 8 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 3 )	( 0 )	( 3 )	( 0 )
	accessory cortical nodule	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )
	focal fatty change:cortex	7	1	0	0	5	0	0	0	7	0	0	0	6	1	0	0
		( 17 )	( 2 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )	( 18 )	( 0 )	( 0 )	( 0 )	( 16 )	( 3 )	( 0 )	( 0 )
[Reproductive system]																	
testis		<42>				<38>				<40>				<37>			
	atrophy	3	2	0	0	7	0	0	0	2	0	0	0	4	1	0	0
		( 7 )	( 5 )	( 0 )	( 0 )	( 18 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 11 )	( 3 )	( 0 )	( 0 )

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

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

b : Number of animals with lesion

( c ) c : b / a \* 100

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 15

Organ	Findings	Control No. of Animals on Study 42 Grade				200 ppm 38				400 ppm 40				800 ppm 37			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Reproductive system]																	
testis	mineralization	<42>				<38>				<40>				<37>			
		0	1	0	0	3	0	0	0	1	0	0	0	1	1	0	0
		( 0 )	( 2 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 3 )	( 3 )	( 0 )	( 0 )
	interstitial cell hyperplasia	<42>				<38>				<40>				<37>			
		4	0	0	0	3	0	0	0	2	0	0	0	6	0	0	0
		( 10 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 16 )	( 0 )	( 0 )	( 0 )
prostate	inflammation	<42>				<38>				<40>				<37>			
		18	0	0	0	21	0	0	0	12	0	0	0	12	0	0	0
		( 43 )	( 0 )	( 0 )	( 0 )	( 55 )	( 0 )	( 0 )	( 0 )	( 30 )	( 0 )	( 0 )	( 0 )	( 32 )	( 0 )	( 0 )	( 0 )
	hyperplasia	<42>				<38>				<40>				<37>			
		6	4	0	0	5	4	0	0	1	1	0	0	2	1	0	0
		( 14 )	( 10 )	( 0 )	( 0 )	( 13 )	( 11 )	( 0 )	( 0 )	( 3 )	( 3 )	( 0 )	( 0 )	( 5 )	( 3 )	( 0 )	( 0 )
mammary gl	duct ectasia	<42>				<38>				<40>				<37>			
		0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )
	galactoceles	<42>				<38>				<40>				<37>			
		3	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
		( 7 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
prep/cli gl	squamous cell hyperplasia	<42>				<38>				<40>				<37>			
		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 16

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	42				38				40				37			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Nervous system]																		
brain			<42>				<38>				<40>				<37>			
	hemorrhage		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	vacuolic change		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)
[Special sense organs/appendage]																		
eye			<42>				<38>				<40>				<37>			
	cataract		4	0	0	0	3	0	0	0	1	0	0	0	1	1	0	0
			( 10)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)	( 3)	( 3)	( 0)	( 0)
	retinal atrophy		0	0	4	0	0	3	2	0	0	2	0	0	1	0	2	0
			( 0)	( 0)	( 10)	( 0)	( 0)	( 8)	( 5)	( 0)	( 0)	( 5)	( 0)	( 0)	( 3)	( 0)	( 5)	( 0)
	keratitis		2	0	0	0	2	0	0	0	0	0	0	0	1	0	0	0
			( 5)	( 0)	( 0)	( 0)	( 5)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)
Harder gl			<42>				<38>				<40>				<37>			
	degeneration		2	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 5)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

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



STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 17

Organ	Findings	Control No. of Animals on Study 42 Grade				200 ppm 38				400 ppm 40				800 ppm 37			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Special sense organs/appendage]																	
Harder gl		<42>				<38>				<40>				<37>			
	Lymphocytic infiltration	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )
		<42>				<38>				<40>				<37>			
	granulation	0	1	0	0	0	0	0	0	1	0	0	0	2	0	0	0
		( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )
nasolacr d		<42>				<38>				<40>				<37>			
	inflammation	0	0	0	0	1	0	0	0	3	0	0	0	3	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )
[Musculoskeletal system]																	
bone		<42>				<38>				<40>				<37>			
	fracture	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )
		<42>				<38>				<40>				<37>			
	osteodystrophy	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 )
		<42>				<38>				<40>				<37>			
	osteosclerosis	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 18

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	42				38				40				37			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Organ_____	Findings_____		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>																		
[Body cavities]																		
peritoneum			<42>				<38>				<40>				<37>			
	peritonitis		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 )	( 0 )	( 0 )

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

(HPT150)

BAIS3

APPENDIX J 4

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

STUDY NO. : 0286  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 22

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	49				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Integumentary system/appandage]																		
skin/app			<49>				<50>				<50>				<50>			
	hyperplasia:epidermis		0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )
[Respiratory system]																		
nasal cavit			<49>				<50>				<50>				<50>			
	thrombus		0	1	0	0	2	1	0	0	4	0	0	0	0	0	0	0
			( 0 )	( 2 )	( 0 )	( 0 )	( 4 )	( 2 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	mineralization		15	0	0	0	40	1	0	0 **	44	3	0	0 **	18	1	0	0
			( 31 )	( 0 )	( 0 )	( 0 )	( 80 )	( 2 )	( 0 )	( 0 )	( 88 )	( 6 )	( 0 )	( 0 )	( 36 )	( 2 )	( 0 )	( 0 )
	goblet cell hyperplasia		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	eosinophilic change:olfactory epithelium		15	28	4	0	22	19	1	0 *	37	10	0	0 **	6	28	3	0 **
			( 31 )	( 57 )	( 8 )	( 0 )	( 44 )	( 38 )	( 2 )	( 0 )	( 74 )	( 20 )	( 0 )	( 0 )	( 12 )	( 56 )	( 6 )	( 0 )
	eosinophilic change:respiratory epithelium		33	2	0	0	30	2	0	0	35	2	0	0	28	6	0	0
			( 67 )	( 4 )	( 0 )	( 0 )	( 60 )	( 4 )	( 0 )	( 0 )	( 70 )	( 4 )	( 0 )	( 0 )	( 56 )	( 12 )	( 0 )	( 0 )
	inflammation:foreign body		5	0	0	0	6	2	0	0	5	0	0	0	0	0	0	0
			( 10 )	( 0 )	( 0 )	( 0 )	( 12 )	( 4 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0286  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 23

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	49				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
nasal cavit			<49>				<50>				<50>				<50>			
	inflammation:squamous epithelium		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	respiratory metaplasia:olfactory epithelium		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	respiratory metaplasia:gland		41	0	0	0	41	0	0	0	45	0	0	0	34	0	0	0
			( 84)	( 0)	( 0)	( 0)	( 82)	( 0)	( 0)	( 0)	( 90)	( 0)	( 0)	( 0)	( 68)	( 0)	( 0)	( 0)
	squamous cell metaplasia:respiratory epithelium		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	ulcer:squamous epithelium		1	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
			( 2)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	ulcer:respiratory epithelium		0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0
			( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	hyperplasia:respiratory epithelium		0	0	0	0	0	0	0	0	2	0	0	0	1	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)
larynx			<49>				<50>				<50>				<50>			
	inflammation		11	0	0	0	4	0	0	0	2	0	0	0 *	8	0	0	0
			( 22)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)	( 16)	( 0)	( 0)	( 0)

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

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

b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 24

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	49				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
lung			<49>				<50>				<50>				<50>			
	congestion		2	2	0	0	1	0	0	0	1	2	0	0	5	4	0	0
			( 4 )	( 4 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 4 )	( 0 )	( 0 )	( 10 )	( 8 )	( 0 )	( 0 )
	hemorrhage		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	edema		2	0	0	0	2	0	0	0	2	0	0	0	1	0	0	0
			( 4 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	deposit of hemosiderin		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	inflammatory infiltration		0	0	0	0	2	0	0	0	1	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	osseous metaplasia		0	0	0	0	2	0	0	0	2	0	0	0	2	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	accumulation of foamy cells		6	0	0	0	2	0	0	0	4	0	0	0	7	1	0	0
			( 12 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 14 )	( 2 )	( 0 )	( 0 )
	interstitial pneumonia		0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 25

Organ	Findings	Control No. of Animals on Study Grade				200 ppm 50				400 ppm 50				800 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																	
Lung	bronchiolar-alveolar cell hyperplasia	<49>				<50>				<50>				<50>			
		0	0	0	0	0	1	0	0	2	1	0	0	1	1	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 4 )	( 2 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )
[Hematopoietic system]																	
bone marrow	congestion	<49>				<50>				<50>				<50>			
		0	0	0	0	0	0	0	0	0	0	0	0	2	9	0	0 **
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 18 )	( 0 )	( 0 )
	hemorrhage	<49>				<50>				<50>				<50>			
		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	granulation	<49>				<50>				<50>				<50>			
		3	0	0	0	7	1	0	0	9	4	0	0 *	9	4	0	0 *
		( 6 )	( 0 )	( 0 )	( 0 )	( 14 )	( 2 )	( 0 )	( 0 )	( 18 )	( 8 )	( 0 )	( 0 )	( 18 )	( 8 )	( 0 )	( 0 )
	increased hematopoiesis	<49>				<50>				<50>				<50>			
		3	0	0	0	7	0	0	0	4	0	0	0	3	1	0	0
		( 6 )	( 0 )	( 0 )	( 0 )	( 14 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 6 )	( 2 )	( 0 )	( 0 )
	myelofibrosis	<49>				<50>				<50>				<50>			
		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
Lymph node																	
	deposit of hemosiderin	<49>				<50>				<50>				<50>			
		0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )

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

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

b b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 26

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	49				50				50				50			
Organ_____	Findings_____	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
<hr/>																		
[Hematopoietic system]																		
Lymph node			<49>				<50>				<50>				<50>			
	granulation		2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	5 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)
	mastcell hyperplasia		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)
	lymphadenitis		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	follicular hyperplasia		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
thymus	hemorrhage		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	9 ( 18)	1 ( 2)	0 ( 0)	0 ( 0) **
			<49>				<50>				<50>				<50>			
spleen	ectopic tissue		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
			<49>				<50>				<50>				<50>			
	deposit of hemosiderin		25 ( 51)	11 ( 22)	1 ( 2)	0 ( 0)	31 ( 62)	5 ( 10)	0 ( 0)	0 ( 0)	34 ( 68)	3 ( 6)	0 ( 0)	0 ( 0)	30 ( 60)	0 ( 0)	0 ( 0)	0 ( 0) **

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



STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 27

		Group Name No. of Animals on Study	Control 49				200 ppm 50				400 ppm 50				800 ppm 50			
Organ_____	Findings_____	Grade	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)
[Hematopoietic system]																		
spleen			<49>				<50>				<50>				<50>			
	focal lymphoid hyperplasia		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	extramedullary hematopoiesis		25 ( 51 )	13 ( 27 )	2 ( 4 )	0 ( 0 )	32 ( 64 )	4 ( 8 )	4 ( 8 )	0 ( 0 )	36 ( 72 )	4 ( 8 )	1 ( 2 )	0 ( 0 )	26 ( 52 )	4 ( 8 )	1 ( 2 )	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 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )
[Circulatory system]																		
heart			<49>				<50>				<50>				<50>			
	atrophy		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )
	hemorrhage		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	4 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	edema		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	thrombus		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 28

Organ	Findings	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	49				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Circulatory system]																		
heart			<49>				<50>				<50>				<50>			
	necrosis:focal		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	mineralization		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	3 ( 6 )	1 ( 2 )	0 ( 0 )	0 ( 0 )
	inflammatory cell nest		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	myocardial fibrosis		33 ( 67 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	26 ( 52 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	21 ( 42 )	0 ( 0 )	0 ( 0 )	0 * ( 0 )	26 ( 52 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
[Digestive system]																		
tooth			<49>				<50>				<50>				<50>			
	inflammation		1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	dysplasia		1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
tongue			<49>				<50>				<50>				<49>			
	ulcer		1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )

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

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

b b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 29

Organ	Findings	Control No. of Animals on Study Grade				200 ppm 50				400 ppm 50				800 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																	
stomach		<49>				<50>				<50>				<50>			
	hemorrhage	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )
	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 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	ulcer:forestomach	1	2	1	0	0	1	1	0	1	1	1	0	0	0	0	0
		( 2 )	( 4 )	( 2 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 2 )	( 2 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	hyperplasia:forestomach	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	erosion:glandular stomach	1	0	0	0	2	0	0	0	2	0	0	0	1	0	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	ulcer:glandular stomach	4	0	0	0	1	0	0	0	1	1	0	0	1	0	0	0
		( 8 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	dilated glands	4	0	0	0	3	0	0	0	2	0	0	0	0	0	0	0
		( 8 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
small intes		<49>				<50>				<50>				<50>			
	erosion	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

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

b b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 30

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	49				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																		
small intes			<49>				<50>				<50>				<50>			
	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 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
large intes			<49>				<50>				<50>				<50>			
	invagination		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
liver			<49>				<50>				<50>				<50>			
	herniation		5	0	0	0	3	0	0	0	7	0	0	0	3	0	0	0
			( 10 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 14 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )
	hemorrhage		3	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 )
	peliosis-like lesion		0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )
	necrosis:central		0	0	0	0	3	0	0	0	1	1	0	0	0	0	13	0 **
			( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 26 )	( 0 )
	necrosis:focal		0	0	0	0	2	0	0	0	0	1	0	0	3	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 31

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	49				50				50				50			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																		
Liver			<49>				<50>				<50>				<50>			
	necrosis: single cell		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	fatty change		0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 2 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	inflammatory infiltration		0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	lymphocytic infiltration		3	0	0	0	20	0	0	0 **	20	0	0	0 **	3	0	0	0
			( 6 )	( 0 )	( 0 )	( 0 )	( 40 )	( 0 )	( 0 )	( 0 )	( 40 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )
	granulation		25	1	1	0	33	0	0	0	27	1	1	0	19	3	0	0
			( 51 )	( 2 )	( 2 )	( 0 )	( 66 )	( 0 )	( 0 )	( 0 )	( 54 )	( 2 )	( 2 )	( 0 )	( 38 )	( 6 )	( 0 )	( 0 )
	extramedullary hematopoiesis		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	clear cell focus		2	1	0	0	14	9	0	0 **	15	18	0	0 **	0	21	12	0 **
			( 4 )	( 2 )	( 0 )	( 0 )	( 28 )	( 18 )	( 0 )	( 0 )	( 30 )	( 36 )	( 0 )	( 0 )	( 0 )	( 42 )	( 24 )	( 0 )
	acidophilic cell focus		0	0	0	0	3	1	0	0	8	2	0	0 **	4	14	2	0 **
			( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 2 )	( 0 )	( 0 )	( 16 )	( 4 )	( 0 )	( 0 )	( 8 )	( 28 )	( 4 )	( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 32

Organ	Findings	Control No. of Animals on Study 49 Grade				200 ppm 50				400 ppm 50				800 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																	
Liver	basophilic cell focus	<49>				<50>				<50>				<50>			
		20	3	0	0	15	12	0	0 *	11	2	2	0	5	17	7	0 **
		( 41)	( 6)	( 0)	( 0)	( 30)	( 24)	( 0)	( 0)	( 22)	( 4)	( 4)	( 0)	( 10)	( 34)	( 14)	( 0)
	vacuolated cell focus	0	0	0	0	0	0	0	0	0	1	0	0	2	1	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 4)	( 2)	( 0)	( 0)
	mixed cell focus	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)
	spongiosis hepatitis	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)
	bile duct hyperplasia	25	0	0	0	32	2	0	0	17	1	0	0	33	1	0	0
		( 51)	( 0)	( 0)	( 0)	( 64)	( 4)	( 0)	( 0)	( 34)	( 2)	( 0)	( 0)	( 66)	( 2)	( 0)	( 0)
	bile ductular proliferation	0	0	0	0	1	0	0	0	3	0	0	0	3	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)
	cholangiofibrosis	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 4)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	biliary 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)	( 4)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 33

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	49				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																		
liver		<49>					<50>				<50>				<50>			
	regenerative hyperplasia	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	2 ( 4)	2 ( 4)	0 ( 0)	
pancreas		<49>					<50>				<50>				<50>			
	atrophy	1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)	3 ( 6)	1 ( 2)	0 ( 0)	0 ( 0)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	
	islet cell hyperplasia	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	
[Urinary system]																		
kidney		<49>					<50>				<50>				<50>			
	infarct	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	
	hyaline droplet	8 ( 16)	0 ( 0)	0 ( 0)	0 ( 0)	10 ( 20)	1 ( 2)	0 ( 0)	0 ( 0)	19 ( 38)	0 ( 0)	0 ( 0)	0 ( 0)	0 * ( 0)	12 ( 24)	0 ( 0)	0 ( 0)	0 ( 0)
	deposit of hemosiderin	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 34

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	49				50				50				50			
Organ_____	Findings_____	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Urinary system]																		
kidney			<49>				<50>				<50>				<50>			
	chronic nephropathy		12 ( 24)	18 ( 37)	3 ( 6)	1 ( 2)	25 ( 50)	5 ( 10)	1 ( 2)	0 ** ( 0)	16 ( 32)	6 ( 12)	0 ( 0)	0 ** ( 0)	9 ( 18)	20 ( 40)	6 ( 12)	0 ( 0)
	hydronephrosis		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	papillary necrosis		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	mineralization:cortico-medullary junction		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	mineralization:papilla		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	mineralization:pelvis		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	urothelial hyperplasia:pelvis		2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	
urin bladd			<49>				<48>				<50>				<50>			
	dilatation		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)

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

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

b : Number of animals with lesion

( c ) c : b / a \* 100

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



STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 35

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	49				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Urinary system]																		
urin bladd			<49>				<48>				<50>				<50>			
	hemorrhage		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	lymphocytic infiltration		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	simple hyperplasia:transitional epithelium		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
[Endocrine system]																		
pituitary			<49>				<50>				<50>				<50>			
	angiectasis		2	4	0	0	2	1	1	0	1	0	0	0	1	0	0	0
			( 4 )	( 8 )	( 0 )	( 0 )	( 4 )	( 2 )	( 2 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	hemorrhage		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	cyst		20	3	0	0	17	5	1	0	16	2	0	0	6	2	0	0 **
			( 41 )	( 6 )	( 0 )	( 0 )	( 34 )	( 10 )	( 2 )	( 0 )	( 32 )	( 4 )	( 0 )	( 0 )	( 12 )	( 4 )	( 0 )	( 0 )
	hyperplasia		5	4	2	0	4	5	2	0	4	3	2	0	4	1	0	0
			( 10 )	( 8 )	( 4 )	( 0 )	( 8 )	( 10 )	( 4 )	( 0 )	( 8 )	( 6 )	( 4 )	( 0 )	( 8 )	( 2 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 36

Organ	Findings	Control No. of Animals on Study 49 Grade				200 ppm 50				400 ppm 50				800 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Endocrine system]																	
pituitary		<49>				<50>				<50>				<50>			
	Rathke pouch	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)
	focal hypertrophy	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
thyroid		<49>				<50>				<50>				<50>			
	ultimibranhial body remanet	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	C-cell hyperplasia	8 ( 16)	2 ( 4)	1 ( 2)	0 ( 0)	13 ( 26)	5 ( 10)	0 ( 0)	0 ( 0)	5 ( 10)	1 ( 2)	2 ( 4)	0 ( 0)	5 ( 10)	1 ( 2)	0 ( 0)	0 ( 0)
	focal follicular cell hyperplasia	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
adrenal		<49>				<50>				<50>				<50>			
	angiectasis	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	hemorrhage	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)

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

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

Organ	Findings	Group Name	Control				200 ppm				400 ppm				800 ppm				
		No. of Animals on Study	49				50				50				50				
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	
[Endocrine system]																			
adrenal			<49>				<50>				<50>				<50>				
	peliosis-like lesion		0	0	0	0	1	0	0	0	2	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	extramedullary hematopoiesis		0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0	
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )
	hyperplasia:cortical cell		6	0	0	0	6	0	0	0	1	0	0	0	3	0	0	0	
			( 12 )	( 0 )	( 0 )	( 0 )	( 12 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 0 )
hyperplasia:medulla		2	1	0	0	1	0	0	0	0	0	0	0	3	0	0	0		
		( 4 )	( 2 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 0 )	
accessory cortical nodule		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
focal fatty change:cortex		13	1	1	0	5	2	0	0	4	0	0	0 *	7	0	0	0		
		( 27 )	( 2 )	( 2 )	( 0 )	( 10 )	( 4 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 14 )	( 0 )	( 0 )	( 0 )	( 0 )	
necrosis:cortex		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0		
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	
[Reproductive system]																			
ovary			<49>				<50>				<50>				<50>				
	cyst		1	0	0	0	3	0	0	0	3	0	0	0	1	0	0	0	
		( 2 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	

Grade

< a >

b

( c )

1 : Slight

a : Number of animals examined at the site

b : Number of animals with lesion

c : b / a \* 100

2 : Moderate

3 : Marked

4 : Severe

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 38

Organ	Findings	Control No. of Animals on Study Grade				200 ppm 50				400 ppm 50				800 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Reproductive system]																	
ovary	Lymphocytic infiltration	<49>				<50>				<50>				<50>			
		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
uterus	hyperplasia:gland	<49>				<50>				<50>				<50>			
		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	cystic endometrial hyperplasia	13	0	0	0	12	0	0	0	15	2	0	0	13	0	0	0
		( 27 )	( 0 )	( 0 )	( 0 )	( 24 )	( 0 )	( 0 )	( 0 )	( 30 )	( 4 )	( 0 )	( 0 )	( 26 )	( 0 )	( 0 )	( 0 )
mammary gl	inflammation	<49>				<50>				<50>				<50>			
		0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	hyperplasia	0	1	0	0	1	1	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 2 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	galactoceles	1	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 )	( 2 )	( 0 )	( 0 )	( 0 )
[Nervous system]																	
brain	vacuolic change	<49>				<50>				<50>				<50>			
		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 39

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	49				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Nervous system]																		
brain			<49>				<50>				<50>				<50>			
	perivascular inflammation		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
[Special sense organs/appendage]																		
eye			<49>				<50>				<50>				<50>			
	cataract		4	0	0	0	3	0	0	0	3	0	0	0	3	0	0	0
			( 8)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)
	retinal atrophy		1	2	2	0	0	0	3	0	0	3	2	0	0	1	2	0
			( 2)	( 4)	( 4)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 6)	( 4)	( 0)	( 0)	( 2)	( 4)	( 0)
	keratitis		6	0	0	0	2	0	0	0	5	0	0	0	3	0	0	0
			( 12)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)
	iritis		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
Harder gl			<49>				<50>				<50>				<50>			
	degeneration		8	0	0	0	5	0	0	0	5	0	0	0	8	1	0	0
			( 16)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 16)	( 2)	( 0)	( 0)

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

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

b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0286  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 40

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	49				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Special sense organs/appendage]																		
Harder gl			<49>				<50>				<50>				<50>			
	lymphocytic infiltration		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	granulation		2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)
nasolacr d			<49>				<50>				<50>				<50>			
	inflammation		8 ( 16)	0 ( 0)	0 ( 0)	0 ( 0)	7 ( 14)	0 ( 0)	0 ( 0)	0 ( 0)	5 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	5 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)
	squamous cell hyperplasia		4 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
[Musculoskeletal system]																		
bone			<49>				<50>				<50>				<50>			
	ostitis fibrosa		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	osteosclerosis		4 ( 8)	2 ( 4)	0 ( 0)	0 ( 0)	2 ( 4)	2 ( 4)	0 ( 0)	0 ( 0)	3 ( 6)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 * ( 0)

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

APPENDIX J 5

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 15

Organ	Findings	Control No. of Animals on Study Grade				200 ppm 12				400 ppm 12				800 ppm 20			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																	
nasal cavit		< 7>				<12>				<12>				<20>			
	thrombus	0 ( 0 )	1 ( 14 )	0 ( 0 )	0 ( 0 )	2 ( 17 )	1 ( 8 )	0 ( 0 )	0 ( 0 )	2 ( 17 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	mineralization	4 ( 57 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	9 ( 75 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	10 ( 83 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	4 ( 20 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	eosinophilic change:olfactory epithelium	2 ( 29 )	4 ( 57 )	0 ( 0 )	0 ( 0 )	6 ( 50 )	2 ( 17 )	0 ( 0 )	0 ( 0 )	8 ( 67 )	2 ( 17 )	0 ( 0 )	0 ( 0 )	4 ( 20 )	2 ( 10 )	1 ( 5 )	0 * ( 0 )
	eosinophilic change:respiratory epithelium	4 ( 57 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	5 ( 42 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	6 ( 50 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	3 ( 15 )	1 ( 5 )	0 ( 0 )	0 ( 0 )
	inflammation:foreign body	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	respiratory metaplasia:olfactory epithelium	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	respiratory metaplasia:gland	3 ( 43 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	8 ( 67 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	11 ( 92 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	8 ( 40 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	squamous cell metaplasia:respiratory epithelium	1 ( 14 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )

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



STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 16

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	7				12				12				20			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
nasal cavit		< 7>					<12>				<12>				<20>			
	ulcer:squamous epithelium	1	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0
		( 14)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	ulcer:respiratory epithelium	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
		( 0)	( 14)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	hyperplasia:respiratory epithelium	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 5)	( 0)	( 0)	( 0)	( 0)
larynx		< 7>					<12>				<12>				<20>			
	inflammation	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
lung		< 7>					<12>				<12>				<20>			
	congestion	1	1	0	0	1	0	0	0	1	2	0	0	5	4	0	0	0
		( 14)	( 14)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 8)	( 17)	( 0)	( 0)	( 25)	( 20)	( 0)	( 0)	( 0)
	hemorrhage	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	edema	1	0	0	0	2	0	0	0	2	0	0	0	1	0	0	0	0
		( 14)	( 0)	( 0)	( 0)	( 17)	( 0)	( 0)	( 0)	( 17)	( 0)	( 0)	( 0)	( 5)	( 0)	( 0)	( 0)	( 0)

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

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

b b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 17

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	7				12				12				20			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
lung			< 7>				<12>				<12>				<20>			
	deposit of hemosiderin		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 ( 5 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	inflammatory infiltration		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 17 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	osseous metaplasia		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 5 )	0 ( 0 )	0 ( 0 )
	accumulation of foamy cells		2 ( 29 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 5 )	1 ( 5 )	0 ( 0 )	0 ( 0 )
	interstitial pneumonia		0 ( 0 )	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 ( 5 )	0 ( 0 )	0 ( 0 )
	bronchiolar-alveolar cell hyperplasia		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
[Hematopoietic system]																		
bone marrow			< 7>				<12>				<12>				<20>			
	congestion		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 10 )	9 ( 45 )	0 ( 0 )	0 * ( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 18

Organ	Findings	Control No. of Animals on Study Grade				200 ppm 12				400 ppm 12				800 ppm 20			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]																	
bone marrow		< 7>				<12>				<12>				<20>			
	hemorrhage	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)	( 0)	( 0)	( 0)	( 0)	( 0)
	granulation	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)	( 10)	( 0)	( 0)	( 0)
	increased hematopoiesis	1	0	0	0	5	0	0	0	3	0	0	0	1	1	0	0
		( 14)	( 0)	( 0)	( 0)	( 42)	( 0)	( 0)	( 0)	( 25)	( 0)	( 0)	( 0)	( 5)	( 5)	( 0)	( 0)
Lymph node		< 7>				<12>				<12>				<20>			
	deposit of hemosiderin	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)	( 10)	( 0)	( 0)	( 0)
	granulation	0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 5)	( 0)	( 0)	( 0)
	mastocell hyperplasia	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)	( 10)	( 0)	( 0)	( 0)
	follicular hyperplasia	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)	( 0)	( 0)	( 0)	( 0)
thymus		< 7>				<12>				<12>				<20>			
	hemorrhage	0	0	0	0	0	0	0	0	1	0	0	0	9	1	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 45)	( 5)	( 0)	( 0)

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

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

b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 19

		Group Name No. of Animals on Study Grade				200 ppm 12				400 ppm 12				800 ppm 20			
Organ_____	Findings_____	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)
[Hematopoietic system]																	
spleen		< 7>				<12>				<12>				<20>			
	deposit of hemosiderin	2 ( 29)	1 ( 14)	1 ( 14)	0 ( 0)	2 ( 17)	1 ( 8)	0 ( 0)	0 ( 0)	3 ( 25)	1 ( 8)	0 ( 0)	0 ( 0)	8 ( 40)	0 ( 0)	0 ( 0)	0 ( 0)
	extramedullary hematopoiesis	1 ( 14)	1 ( 14)	1 ( 14)	0 ( 0)	3 ( 25)	0 ( 0)	4 ( 33)	0 ( 0)	4 ( 33)	0 ( 0)	1 ( 8)	0 ( 0)	2 ( 10)	3 ( 15)	1 ( 5)	0 ( 0)
[Circulatory system]																	
heart		< 7>				<12>				<12>				<20>			
	hemorrhage	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 20)	0 ( 0)	0 ( 0)	0 ( 0)
	edema	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 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
	thrombus	0 ( 0)	0 ( 0)	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 ( 5)	0 ( 0)
	necrosis:focal	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	mineralization	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 10)	1 ( 5)	0 ( 0)	0 ( 0)

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 20

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	7				12				12				20			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Circulatory system]																		
heart	myocardial fibrosis		< 7>				<12>				<12>				<20>			
			3	0	0	0	4	0	0	0	5	0	0	0	9	0	0	0
			( 43)	( 0)	( 0)	( 0)	( 33)	( 0)	( 0)	( 0)	( 42)	( 0)	( 0)	( 0)	( 45)	( 0)	( 0)	( 0)
[Digestive system]																		
tooth	inflammation		< 7>				<12>				<12>				<20>			
			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)	( 0)	( 0)	( 0)	( 0)	( 0)
tongue	ulcer		< 7>				<12>				<12>				<20>			
			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)	( 0)	( 0)	( 0)	( 0)	( 0)
stomach	hemorrhage		< 7>				<12>				<12>				<20>			
			0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 5)	( 0)	( 0)
	ulcer:forestomach		1	1	1	0	0	1	1	0	1	0	1	0	0	0	0	0 *
			( 14)	( 14)	( 14)	( 0)	( 0)	( 8)	( 8)	( 0)	( 8)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)
	hyperplasia:forestomach		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)	( 0)	( 0)	( 0)	( 0)	( 0)

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 21

		Group Name No. of Animals on Study Grade				Control 7				200 ppm 12				400 ppm 12				800 ppm 20			
Organ_____	Findings_____	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)				
[Digestive system]																					
stomach		< 7>				<12>				<12>				<20>							
	erosion:glandular stomach	1 ( 14 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )				
	ulcer:glandular stomach	3 ( 43 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 5 )	0 ( 0 )	0 ( 0 )	0 ( 0 )				
	dilated glands	1 ( 14 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 17 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )				
small intes		< 7>				<12>				<12>				<20>							
	erosion	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )				
large intes		< 7>				<12>				<12>				<20>							
	invagination	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )				
liver		< 7>				<12>				<12>				<20>							
	herniation	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 17 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 10 )	0 ( 0 )	0 ( 0 )	0 ( 0 )				
	peliosis-like lesion	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 5 )	0 ( 0 )	0 ( 0 )				

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

STUDY NO. : 0296  
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	Control No. of Animals on Study Grade				200 ppm 12				400 ppm 12				800 ppm 20			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																	
Liver	necrosis:central	< 7>				<12>				<12>				<20>			
		0	0	0	0	3	0	0	0	1	0	0	0	0	0	13	0 *
		( 0 )	( 0 )	( 0 )	( 0 )	( 25 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 65 )	( 0 )
	necrosis:focal	0	0	0	0	1	0	0	0	0	1	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )
	necrosis:single cell	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	inflammatory infiltration	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 17 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	Lymphocytic infiltration	0	0	0	0	2	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 )
	granulation	2	0	0	0	2	0	0	0	1	1	0	0	3	2	0	0
		( 28 )	( 0 )	( 0 )	( 0 )	( 17 )	( 0 )	( 0 )	( 0 )	( 8 )	( 8 )	( 0 )	( 0 )	( 15 )	( 10 )	( 0 )	( 0 )
	clear cell focus	0	0	0	0	0	0	0	0	0	3	0	0	0	4	1	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 25 )	( 0 )	( 0 )	( 0 )	( 20 )	( 5 )	( 0 )
	acidophilic cell focus	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 5 )	( 5 )	( 0 )	( 0 )

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

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

b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 23

Organ	Findings	Control No. of Animals on Study Grade				200 ppm 12				400 ppm 12				800 ppm 20			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																	
Liver		< 7>				<12>				<12>				<20>			
	basophilic cell focus	0	0	0	0	2	1	0	0	2	1	0	0	0	2	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 17 )	( 8 )	( 0 )	( 0 )	( 17 )	( 8 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )
	bile duct hyperplasia	3	0	0	0	5	1	0	0	3	1	0	0	5	1	0	0
		( 43 )	( 0 )	( 0 )	( 0 )	( 42 )	( 8 )	( 0 )	( 0 )	( 25 )	( 8 )	( 0 )	( 0 )	( 25 )	( 5 )	( 0 )	( 0 )
	bile ductular proliferation	0	0	0	0	1	0	0	0	3	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 25 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )
	biliary 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 )	( 0 )
	regenerative hyperplasia	0	0	0	0	0	0	0	0	0	0	0	0	3	1	2	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 15 )	( 5 )	( 10 )	( 0 )
pancreas		< 7>				<12>				<12>				<20>			
	atrophy	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	islet cell hyperplasia	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )
[Urinary system]																	
kidney		< 7>				<12>				<12>				<20>			
	infarct	1	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 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe  
< a > a : Number of animals examined at the site  
b : Number of animals with lesion



STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 24

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	7				12				12				20			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

---

[Urinary system]

kidney

hyaline droplet	< 7>				<12>				<12>				<20>				
	1	0	0	0	0	1	0	0	0	7	0	0	0	1	0	0	0
	( 14)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 58)	( 0)	( 0)	( 0)	( 5)	( 0)	( 0)	( 0)
deposit of hemosiderin	1	0	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)	( 0)	( 0)	( 0)	( 0)	( 0)
chronic nephropathy	1	3	0	0	3	1	0	0	0	2	1	0	0	2	5	0	0
	( 14)	( 43)	( 0)	( 0)	( 25)	( 8)	( 0)	( 0)	( 0)	( 17)	( 8)	( 0)	( 0)	( 10)	( 25)	( 0)	( 0)
hydronephrosis	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	( 14)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
papillary necrosis	1	0	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)	( 0)	( 0)	( 0)	( 0)	( 0)
mineralization:papilla	1	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)	( 0)	( 0)	( 5)	( 0)	( 0)	( 0)
mineralization:pelvis	1	0	0	0	1	0	0	0	0	0	0	0	0	1	0	0	0
	( 14)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 5)	( 0)	( 0)	( 0)
urothelial hyperplasia:pelvis	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	( 29)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 25

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	7				12				12				20			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Urinary system]																		
urin bladd	dilatation		< 7>				<12>				<12>				<20>			
			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)	( 0)	( 0)	( 0)	( 0)	( 0)
	hemorrhage		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	simple hyperplasia:transitional epithelium		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
[Endocrine system]																		
pituitary	cyst		< 7>				<12>				<12>				<20>			
			1	0	0	0	1	0	0	0	4	0	0	0	0	0	0	0
			( 14)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 33)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	hyperplasia		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)	( 0)	( 0)	( 0)	( 0)	( 0)
	Rathke pouch		1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			( 14)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
thyroid	ultimibranhial body remanet		< 7>				<12>				<12>				<20>			
			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)	( 0)	( 0)	( 0)	( 0)	( 0)

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

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

b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 26

Organ	Findings	Group Name	Control				200 ppm				400 ppm				800 ppm				
		No. of Animals on Study	7				12				12				20				
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	
[Endocrine system]																			
thyroid			< 7>				<12>				<12>				<20>				
	C-cell hyperplasia		1 ( 14)	1 ( 14)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 * ( 0)
adrenal			< 7>				<12>				<12>				<20>				
	hemorrhage		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	extramedullary hematopoiesis		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)	
	hyperplasia:medulla		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 15)	0 ( 0)	0 ( 0)	0 ( 0)	
	focal fatty change:cortex		3 ( 43)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 17)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 * ( 0)	
	necrosis:cortex		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 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)	
[Reproductive system]																			
ovary			< 7>				<12>				<12>				<20>				
	cyst		1 ( 14)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)	

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

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

b b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 27

Organ	Findings	Control No. of Animals on Study Grade				200 ppm 12				400 ppm 12				800 ppm 20			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Reproductive system]																	
uterus		< 7>				<12>				<12>				<20>			
	cystic endometrial hyperplasia	1 ( 14)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 33)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
mammary gl		< 7>				<12>				<12>				<20>			
	hyperplasia	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	galactoceles	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 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)
[Special sense organs/appendage]																	
eye		< 7>				<12>				<12>				<20>			
	keratitis	1 ( 14)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
Harder gl		< 7>				<12>				<12>				<20>			
	degeneration	3 ( 43)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 17)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)
	granulation	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 28

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	7				12				12				20			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Special sense organs/appendage]																		
nasolacr d			< 7>				<12>				<12>				<20>			
	inflammation		2	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
			( 29)	( 0)	( 0)	( 0)	( 17)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
[Musculoskeletal system]																		
bone			< 7>				<12>				<12>				<20>			
	ostitis fibrosa		1	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0
			( 14)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 5)	( 0)	( 0)	( 0)
	osteosclerosis		2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 29)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

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

(HPT150)

BAIS3

APPENDIX J 6

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 19

Organ	Findings	Control No. of Animals on Study Grade				200 ppm 38				400 ppm 38				800 ppm 30			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Integumentary system/appandage]																	
skin/app		<42>				<38>				<38>				<30>			
	hyperplasia:epidermis	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )
[Respiratory system]																	
nasal cavit		<42>				<38>				<38>				<30>			
	thrombus	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	mineralization	11	0	0	0	31	1	0	0 **	34	3	0	0 **	14	1	0	0
		( 26 )	( 0 )	( 0 )	( 0 )	( 82 )	( 3 )	( 0 )	( 0 )	( 89 )	( 8 )	( 0 )	( 0 )	( 47 )	( 3 )	( 0 )	( 0 )
	goblet cell hyperplasia	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	eosinophilic change:olfactory epithelium	13	24	4	0	16	17	1	0	29	8	0	0 **	2	26	2	0 *
		( 31 )	( 57 )	( 10 )	( 0 )	( 42 )	( 45 )	( 3 )	( 0 )	( 76 )	( 21 )	( 0 )	( 0 )	( 7 )	( 87 )	( 7 )	( 0 )
	eosinophilic change:respiratory epithelium	29	2	0	0	25	2	0	0	29	2	0	0	25	5	0	0 **
		( 69 )	( 5 )	( 0 )	( 0 )	( 66 )	( 5 )	( 0 )	( 0 )	( 76 )	( 5 )	( 0 )	( 0 )	( 83 )	( 17 )	( 0 )	( 0 )
	inflammation:foreign body	5	0	0	0	5	2	0	0	4	0	0	0	0	0	0	0
		( 12 )	( 0 )	( 0 )	( 0 )	( 13 )	( 5 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 20

Organ	Findings	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	42				38				38				30			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
nasal cavit			<42>				<38>				<38>				<30>			
	inflammation:squamous epithelium		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	respiratory metaplasia:gland		38	0	0	0	33	0	0	0	34	0	0	0	26	0	0	0
			( 90)	( 0)	( 0)	( 0)	( 87)	( 0)	( 0)	( 0)	( 89)	( 0)	( 0)	( 0)	( 87)	( 0)	( 0)	( 0)
	hyperplasia:respiratory epithelium		0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 5)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
larynx			<42>				<38>				<38>				<30>			
	inflammation		11	0	0	0	3	0	0	0	2	0	0	0 *	8	0	0	0
			( 26)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 5)	( 0)	( 0)	( 0)	( 27)	( 0)	( 0)	( 0)
lung			<42>				<38>				<38>				<30>			
	congestion		1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 2)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	edema		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	osseous metaplasia		0	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)

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



STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 21

		Control No. of Animals on Study 42 Grade				200 ppm 38				400 ppm 38				800 ppm 30			
Organ	Findings	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)
[Respiratory system]																	
lung		<42>				<38>				<38>				<30>			
	accumulation of foamy cells	4 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 11)	0 ( 0)	0 ( 0)	0 ( 0)	6 ( 20)	0 ( 0)	0 ( 0)	0 ( 0)
	interstitial pneumonia	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	bronchiolar-alveolar cell hyperplasia	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	1 ( 3)	1 ( 3)	0 ( 0)	0 ( 0)	1 ( 3)	1 ( 3)	0 ( 0)	0 ( 0)
[Hematopoietic system]																	
bone marrow		<42>				<38>				<38>				<30>			
	hemorrhage	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	granulation	3 ( 7)	0 ( 0)	0 ( 0)	0 ( 0)	7 ( 18)	1 ( 3)	0 ( 0)	0 ( 0)	9 ( 24)	4 ( 11)	0 ( 0)	0 ( 0) **	7 ( 23)	4 ( 13)	0 ( 0)	0 ( 0) **
	increased hematopoiesis	2 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 7)	0 ( 0)	0 ( 0)	0 ( 0)
	myelofibrosis	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)

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

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

lymph node	<42>				<38>				<38>				<30>			
granulation	2 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	5 ( 13)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)
lymphadenitis	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
spleen	<42>				<38>				<38>				<30>			
ectopic tissue	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
deposit of hemosiderin	23 ( 55)	10 ( 24)	0 ( 0)	0 ( 0)	29 ( 76)	4 ( 11)	0 ( 0)	0 ( 0)	31 ( 82)	2 ( 5)	0 ( 0)	0 ( 0) *	22 ( 73)	0 ( 0)	0 ( 0)	0 ( 0) *
focal lymphoid hyperplasia	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
extramedullary hematopoiesis	24 ( 57)	12 ( 29)	1 ( 2)	0 ( 0)	29 ( 76)	4 ( 11)	0 ( 0)	0 ( 0)	32 ( 84)	4 ( 11)	0 ( 0)	0 ( 0)	24 ( 80)	1 ( 3)	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)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)

[illegible]

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			

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 23

		Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	42				38				38				30			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Circulatory system]																		
heart			<42>				<38>				<38>				<30>			
	thrombus		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	mineralization		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )
	inflammatory cell nest		0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	myocardial fibrosis		30	0	0	0	22	0	0	0	16	0	0	0 *	17	0	0	0
			( 71 )	( 0 )	( 0 )	( 0 )	( 58 )	( 0 )	( 0 )	( 0 )	( 42 )	( 0 )	( 0 )	( 0 )	( 57 )	( 0 )	( 0 )	( 0 )
[Digestive system]																		
tooth			<42>				<38>				<38>				<30>			
	inflammation		0	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )
	dysplasia		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
stomach			<42>				<38>				<38>				<30>			
	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 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 24

Organ_____	Findings_____	Group Name No. of Animals on Study Grade				Control 42				200 ppm 38				400 ppm 38				800 ppm 30			
		1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)				
[Digestive system]																					
stomach		<42>				<38>				<38>				<30>							
	ulcer:forestomach	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )				
	erosion:glandular stomach	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )				
	ulcer:glandular stomach	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )				
	dilated glands	3 ( 7 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )				
small intes		<42>				<38>				<38>				<30>							
	inflammatory infiltration	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )				
Liver		<42>				<38>				<38>				<30>							
	herniation	5 ( 12 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	3 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	5 ( 13 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )				
	hemorrhage	3 ( 7 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )				

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

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

b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 25

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	42				38				38				30			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

---

[Digestive system]																		
Liver		<42>	<38>				<38>				<30>							
	peliosis-like lesion	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	
	necrosis:central	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	
	necrosis:focal	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 7 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	
	fatty change	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	
	lymphocytic infiltration	3 ( 7 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	18 ( 47 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	20 ( 53 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	3 ( 10 )	0 ( 0 )	0 ( 0 )	
	granulation	23 ( 55 )	1 ( 2 )	1 ( 2 )	0 ( 0 )	31 ( 82 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	26 ( 68 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	16 ( 53 )	1 ( 3 )	0 ( 0 )	
	extramedullary hematopoiesis	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	
clear cell focus	2 ( 5 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	14 ( 37 )	9 ( 24 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	15 ( 39 )	15 ( 39 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	17 ( 57 )	11 ( 37 )	0 ( 0 )	

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

STUDY NO. : 0298  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 26

Organ	Findings	Control No. of Animals on Study Grade				200 ppm 38				400 ppm 38				800 ppm 30			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																	
Liver		<42>				<38>				<38>				<30>			
	acidophilic cell focus	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	3 ( 8 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	8 ( 21 )	2 ( 5 )	0 ( 0 )	0 ** ( 0 )	3 ( 10 )	13 ( 43 )	2 ( 7 )	0 ** ( 0 )
	basophilic cell focus	20 ( 48 )	3 ( 7 )	0 ( 0 )	0 ( 0 )	13 ( 34 )	11 ( 29 )	0 ( 0 )	0 * ( 0 )	9 ( 24 )	1 ( 3 )	2 ( 5 )	0 * ( 0 )	5 ( 17 )	15 ( 50 )	7 ( 23 )	0 ** ( 0 )
	vacuolated cell focus	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	2 ( 7 )	1 ( 3 )	0 ( 0 )	0 ( 0 )
	mixed 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 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )
	spongiosis hepatis	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 7 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	bile duct hyperplasia	22 ( 52 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	27 ( 71 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	14 ( 37 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	28 ( 93 )	0 ( 0 )	0 ( 0 )	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 )	2 ( 7 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	cholangiofibrosis	2 ( 5 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 27

Organ	Findings	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	42				38				38				30			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																		
Liver			<42>				<38>				<38>				<30>			
	biliary cyst		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)
	regenerative hyperplasia		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	
pancreas			<42>				<38>				<38>				<30>			
	atrophy		1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)	3 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
[Urinary system]																		
kidney			<42>				<38>				<38>				<30>			
	hyaline droplet		7 ( 17)	0 ( 0)	0 ( 0)	0 ( 0)	10 ( 26)	0 ( 0)	0 ( 0)	0 ( 0)	12 ( 32)	0 ( 0)	0 ( 0)	0 ( 0)	11 ( 37)	0 ( 0)	0 ( 0)	0 ( 0)
	chronic nephropathy		11 ( 26)	15 ( 36)	3 ( 7)	1 ( 2)	22 ( 58)	4 ( 11)	1 ( 3)	0 * ( 0)	14 ( 37)	5 ( 13)	0 ( 0)	0 * ( 0)	7 ( 23)	15 ( 50)	6 ( 20)	0 ( 0)
	mineralization:cortico-medullary junction		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 28

		Group Name No. of Animals on Study Grade				Control 42				200 ppm 38				400 ppm 38				800 ppm 30			
Organ	Findings	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)				
[Urinary system]																					
urin bladd		<42>				<36>				<38>				<30>							
	lymphocytic infiltration	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )				
[Endocrine system]																					
pituitary		<42>				<38>				<38>				<30>							
	angiectasis	2 ( 5 )	4 ( 10 )	0 ( 0 )	0 ( 0 )	2 ( 5 )	1 ( 3 )	1 ( 3 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )				
	hemorrhage	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )				
	cyst	19 ( 45 )	3 ( 7 )	0 ( 0 )	0 ( 0 )	16 ( 42 )	5 ( 13 )	1 ( 3 )	0 ( 0 )	12 ( 32 )	2 ( 5 )	0 ( 0 )	0 ( 0 )	6 ( 20 )	2 ( 7 )	0 ( 0 )	0 ( 0 )				
	hyperplasia	4 ( 10 )	4 ( 10 )	2 ( 5 )	0 ( 0 )	4 ( 11 )	5 ( 13 )	2 ( 5 )	0 ( 0 )	4 ( 11 )	3 ( 8 )	2 ( 5 )	0 ( 0 )	4 ( 13 )	1 ( 3 )	0 ( 0 )	0 ( 0 )				
	Rathke pouch	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	3 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 7 )	0 ( 0 )	0 ( 0 )	0 ( 0 )				
	focal hypertrophy	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 3 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )				

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



STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 29

Organ	Findings	Control No. of Animals on Study Grade				200 ppm 38				400 ppm 38				800 ppm 30			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Endocrine system]																	
thyroid		<42>				<38>				<38>				<30>			
	ultimibranhial body remanet	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	G-cell hyperplasia	7	1	1	0	13	4	0	0	5	1	2	0	5	1	0	0
		( 17 )	( 2 )	( 2 )	( 0 )	( 34 )	( 11 )	( 0 )	( 0 )	( 13 )	( 3 )	( 5 )	( 0 )	( 17 )	( 3 )	( 0 )	( 0 )
	focal follicular cell hyperplasia	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
adrenal		<42>				<38>				<38>				<30>			
	angiectasis	2	0	0	0	0	0	0	0	4	0	0	0	0	0	0	0
		( 5 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	hemorrhage	0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )
	peliosis-like lesion	0	0	0	0	1	0	0	0	2	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	hyperplasia:cortical cell	6	0	0	0	6	0	0	0	1	0	0	0	3	0	0	0
		( 14 )	( 0 )	( 0 )	( 0 )	( 16 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )
	hyperplasia:medulla	2	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 5 )	( 2 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 30

Organ_____	Findings_____	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	42				38				38				30			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Endocrine system]																		
adrenal			<42>				<38>				<38>				<30>			
	accessory cortical nodule		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	focal fatty change:cortex		10 ( 24)	1 ( 2)	1 ( 2)	0 ( 0)	3 ( 8)	2 ( 5)	0 ( 0)	0 ( 0)	3 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	7 ( 23)	0 ( 0)	0 ( 0)	0 ( 0)
[Reproductive system]																		
ovary			<42>				<38>				<38>				<30>			
	cyst		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	lymphocytic infiltration		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
uterus			<42>				<38>				<38>				<30>			
	hyperplasia:gland		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	cystic endometrial hyperplasia		12 ( 29)	0 ( 0)	0 ( 0)	0 ( 0)	12 ( 32)	0 ( 0)	0 ( 0)	0 ( 0)	11 ( 29)	2 ( 5)	0 ( 0)	0 ( 0)	12 ( 40)	0 ( 0)	0 ( 0)	0 ( 0)

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 31

Organ	Findings	Group Name	Control				200 ppm				400 ppm				800 ppm			
		No. of Animals on Study	42				38				38				30			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Reproductive system]																		
mammary gl			<42>				<38>				<38>				<30>			
	inflammation		0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	hyperplasia		0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 2 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	galactoceles		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
[Nervous system]																		
brain			<42>				<38>				<38>				<30>			
	vacuolic change		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	perivascular inflammation		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
[Special sense organs/appendage]																		
eye			<42>				<38>				<38>				<30>			
	cataract		4	0	0	0	3	0	0	0	3	0	0	0	3	0	0	0
			( 10 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 32

Organ	Findings	Control No. of Animals on Study 42				200 ppm 38				400 ppm 38				800 ppm 30			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Special sense organs/appendage]																	
eye		<42>				<38>				<38>				<30>			
	retinal atrophy	1	2	2	0	0	0	3	0	0	3	2	0	0	1	2	0
		( 2 )	( 5 )	( 5 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 8 )	( 5 )	( 0 )	( 0 )	( 3 )	( 7 )	( 0 )
	keratitis	5	0	0	0	2	0	0	0	5	0	0	0	3	0	0	0
		( 12 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )
	iritis	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 )
Harder gl		<42>				<38>				<38>				<30>			
	degeneration	5	0	0	0	3	0	0	0	5	0	0	0	6	1	0	0
		( 12 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )	( 20 )	( 3 )	( 0 )	( 0 )
	lymphocytic infiltration	0	0	0	0	3	0	0	0	1	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )
	granulation	2	0	0	0	1	0	0	0	1	0	0	0	2	0	0	0
		( 5 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 7 )	( 0 )	( 0 )	( 0 )
nasolacr d		<42>				<38>				<38>				<30>			
	inflammation	6	0	0	0	5	0	0	0	5	0	0	0	5	0	0	0
		( 14 )	( 0 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )	( 17 )	( 0 )	( 0 )	( 0 )

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

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

b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 33

Organ	Findings	Control No. of Animals on Study 42				200 ppm 38				400 ppm 38				800 ppm 30			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

[Special sense organs/appendage]

nasolacr d	squamous cell hyperplasia	<42>				<38>				<38>				<30>			
		4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 10)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

[Musculoskeletal system]

bone	osteosclerosis	<42>				<38>				<38>				<30>			
		2	2	0	0	2	2	0	0	3	1	0	0	0	0	0	0
		( 5)	( 5)	( 0)	( 0)	( 5)	( 5)	( 0)	( 0)	( 8)	( 3)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

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

(HPT150)

BAIS3

APPENDIX K 1

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS-TIME RELATED  
RAT: MALE  
( 2-YEAR STUDY )

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 1

Time-related Weeks	Items	Group Name	Control	200 ppm	400 ppm	800 ppm
0 - 52	NO. OF EXAMINED ANIMALS		1	2	1	4
	NO. OF ANIMALS WITH TUMORS		1	1	0	1
	NO. OF ANIMALS WITH SINGLE TUMORS		1	1	0	1
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	0
	NO. OF BENIGN TUMORS		0	0	0	0
	NO. OF MALIGNANT TUMORS		1	1	0	1
	NO. OF TOTAL TUMORS		1	1	0	1
53 - 78	NO. OF EXAMINED ANIMALS		1	0	1	2
	NO. OF ANIMALS WITH TUMORS		1	0	1	2
	NO. OF ANIMALS WITH SINGLE TUMORS		0	0	1	1
	NO. OF ANIMALS WITH MULTIPLE TUMORS		1	0	0	1
	NO. OF BENIGN TUMORS		3	0	0	3
	NO. OF MALIGNANT TUMORS		0	0	1	1
	NO. OF TOTAL TUMORS		3	0	1	4
79 - 104	NO. OF EXAMINED ANIMALS		6	10	8	7
	NO. OF ANIMALS WITH TUMORS		6	10	8	7
	NO. OF ANIMALS WITH SINGLE TUMORS		1	1	1	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		5	9	7	7
	NO. OF BENIGN TUMORS		7	16	13	11
	NO. OF MALIGNANT TUMORS		4	8	8	7
	NO. OF TOTAL TUMORS		11	24	19	18
105 - 105	NO. OF EXAMINED ANIMALS		42	38	40	37
	NO. OF ANIMALS WITH TUMORS		42	38	40	37
	NO. OF ANIMALS WITH SINGLE TUMORS		18	7	10	7
	NO. OF ANIMALS WITH MULTIPLE TUMORS		24	31	30	30
	NO. OF BENIGN TUMORS		70	77	75	63
	NO. OF MALIGNANT TUMORS		10	9	7	24
	NO. OF TOTAL TUMORS		80	86	82	87

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 2

Time-related Weeks	Items	Group Name	Control	200 ppm	400 ppm	800 ppm
0 - 105	NO. OF EXAMINED ANIMALS		50	50	50	50
	NO. OF ANIMALS WITH TUMORS		50	49	49	47
	NO. OF ANIMALS WITH SINGLE TUMORS		20	9	12	9
	NO. OF ANIMALS WITH MULTIPLE TUMORS		30	40	37	38
	NO. OF BENIGN TUMORS		80	93	88	77
	NO. OF MALIGNANT TUMORS		15	18	14	33
	NO. OF TOTAL TUMORS		95	111	102	110

(HPT070)

BAIS3



APPENDIX K 2

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS-TIME RELATED  
RAT: FEMALE  
( 2-YEAR STUDY )

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 3

Time-related Weeks	Items	Group Name	Control	200 ppm	400 ppm	800 ppm
0 - 52	NO. OF EXAMINED ANIMALS		0	0	1	11
	NO. OF ANIMALS WITH TUMORS		0	0	1	1
	NO. OF ANIMALS WITH SINGLE TUMORS		0	0	1	1
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	0
	NO. OF BENIGN TUMORS		0	0	0	0
	NO. OF MALIGNANT TUMORS		0	0	1	1
	NO. OF TOTAL TUMORS		0	0	1	1
53 - 78	NO. OF EXAMINED ANIMALS		2	1	2	3
	NO. OF ANIMALS WITH TUMORS		2	1	2	0
	NO. OF ANIMALS WITH SINGLE TUMORS		1	1	2	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		1	0	0	0
	NO. OF BENIGN TUMORS		1	0	1	0
	NO. OF MALIGNANT TUMORS		2	1	1	0
	NO. OF TOTAL TUMORS		3	1	2	0
79 - 104	NO. OF EXAMINED ANIMALS		5	11	9	6
	NO. OF ANIMALS WITH TUMORS		5	11	9	4
	NO. OF ANIMALS WITH SINGLE TUMORS		2	5	8	3
	NO. OF ANIMALS WITH MULTIPLE TUMORS		3	6	1	1
	NO. OF BENIGN TUMORS		7	13	4	2
	NO. OF MALIGNANT TUMORS		2	7	7	3
	NO. OF TOTAL TUMORS		9	20	11	5
105 - 105	NO. OF EXAMINED ANIMALS		42	38	38	30
	NO. OF ANIMALS WITH TUMORS		30	26	24	20
	NO. OF ANIMALS WITH SINGLE TUMORS		14	21	15	11
	NO. OF ANIMALS WITH MULTIPLE TUMORS		16	5	9	9
	NO. OF BENIGN TUMORS		41	30	30	24
	NO. OF MALIGNANT TUMORS		7	3	4	9
	NO. OF TOTAL TUMORS		48	33	34	33

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 4

Time-related Weeks	Items	Group Name	Control	200 ppm	400 ppm	800 ppm
0 - 105	NO. OF EXAMINED ANIMALS		49	50	50	50
	NO. OF ANIMALS WITH TUMORS		37	38	36	25
	NO. OF ANIMALS WITH SINGLE TUMORS		17	27	26	15
	NO. OF ANIMALS WITH MULTIPLE TUMORS		20	11	10	10
	NO. OF BENIGN TUMORS		49	43	35	26
	NO. OF MALIGNANT TUMORS		11	11	13	13
	NO. OF TOTAL TUMORS		60	54	48	39

(HPT070)

BAIS3

APPENDIX L 1

HISTOLOGICAL FINDINGS: NEOPLASTIC LESIONS: SUMMARY, RAT: MALE

( 2-YEAR STUDY )

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name No. of animals on Study	Control 50	200 ppm 50	400 ppm 50	800 ppm 50
[Integumentary system/appandage]						
skin/app			<50>	<50>	<50>	<50>
	squamous cell papilloma		0 ( 0%)	1 ( 2%)	1 ( 2%)	0 ( 0%)
	keratoacanthoma		0 ( 0%)	1 ( 2%)	1 ( 2%)	1 ( 2%)
	sebaceous adenoma		2 ( 4%)	0 ( 0%)	0 ( 0%)	0 ( 0%)
	basal cell carcinoma		0 ( 0%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
subcutis			<50>	<50>	<50>	<50>
	fibroma		4 ( 8%)	7 ( 14%)	1 ( 2%)	2 ( 4%)
	myxoma		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
	leiomyosarcoma		1 ( 2%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
	schwannoma:malignant		1 ( 2%)	0 ( 0%)	0 ( 0%)	0 ( 0%)
	sarcoma:NOS		0 ( 0%)	0 ( 0%)	2 ( 4%)	0 ( 0%)
	mastcytoma:malignant		0 ( 0%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
[Respiratory system]						
nasal cavit			<50>	<50>	<50>	<50>
	adenoma		1 ( 2%)	0 ( 0%)	0 ( 0%)	0 ( 0%)
lung			<50>	<50>	<50>	<50>
	bronchiolar-alveolar adenoma		3 ( 6%)	2 ( 4%)	1 ( 2%)	1 ( 2%)

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 2

Organ_____	Findings_____	Group Name No. of animals on Study	Control 50	200 ppm 50	400 ppm 50	800 ppm 50			
[Respiratory system]									
lung			<50>	<50>	<50>	<50>			
	squamous cell carcinoma	0	( 0%)	0	( 0%)	1	( 2%)		
	bronchiolar-alveolar carcinoma	1	( 2%)	0	( 0%)	0	( 0%)		
[Hematopoietic system]									
spleen			<50>	<50>	<50>	<49>			
	mononuclear cell leukemia	3	( 6%)	2	( 4%)	3	( 6%)	4	( 8%)
	hemangiosarcoma	0	( 0%)	0	( 0%)	0	( 0%)	1	( 2%)
[Digestive system]									
oral cavity			<50>	<50>	<50>	<50>			
	squamous cell papilloma	1	( 2%)	0	( 0%)	0	( 0%)	0	( 0%)
	squamous cell carcinoma	0	( 0%)	1	( 2%)	0	( 0%)	1	( 2%)
salivary gl			<50>	<50>	<50>	<50>			
	fibroma	0	( 0%)	1	( 2%)	0	( 0%)	0	( 0%)
liver			<50>	<50>	<50>	<50>			
	hepatocellular adenoma	1	( 2%)	3	( 6%)	13	( 26%)	20	( 40%)
	histiocytic sarcoma	0	( 0%)	0	( 0%)	2	( 4%)	0	( 0%)
	hepatocellular carcinoma	0	( 0%)	1	( 2%)	0	( 0%)	24	( 48%)
pancreas			<50>	<50>	<50>	<50>			
	islet cell adenoma	1	( 2%)	0	( 0%)	2	( 4%)	1	( 2%)

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 3

Organ	Findings	Group Name No. of animals on Study	Control 50	200 ppm 50	400 ppm 50	800 ppm 50
[Digestive system]						
pancreas	acinar cell adenoma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)
	islet cell adenocarcinoma		0 ( 0%)	3 ( 6%)	0 ( 0%)	0 ( 0%)
[Urinary system]						
urin bladd	transitional cell papilloma		<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 1 ( 2%)	<50> 1 ( 2%)
[Endocrine system]						
pituitary	adenoma		<50> 9 ( 18%)	<50> 17 ( 34%)	<50> 4 ( 8%)	<50> 3 ( 6%)
	craniopharyngioma		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
	adenocarcinoma		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
thyroid	C-cell adenoma		<50> 10 ( 20%)	<50> 8 ( 16%)	<50> 9 ( 18%)	<50> 5 ( 10%)
	follicular adenoma		0 ( 0%)	2 ( 4%)	2 ( 4%)	0 ( 0%)
	C-cell carcinoma		1 ( 2%)	0 ( 0%)	0 ( 0%)	0 ( 0%)
	follicular adenocarcinoma		0 ( 0%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
adrenal	pheochromocytoma		<50> 1 ( 2%)	<50> 5 ( 10%)	<50> 4 ( 8%)	<50> 1 ( 2%)

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 4

Organ_____	Findings_____	Group Name No. of animals on Study	Control 50	200 ppm 50	400 ppm 50	800 ppm 50	
[Endocrine system]							
adrenal			<50>	<50>	<50>	<50>	
	ganglioneuroma	1	( 2%)	0	( 0%)	0	( 0%)
	pheochromocytoma:malignant	2	( 4%)	0	( 0%)	1	( 2%)
						0	( 0%)
[Reproductive system]							
testis			<50>	<50>	<50>	<50>	
	interstitial cell tumor	44	( 88%)	43	( 86%)	46	( 92%)
						42	( 84%)
prostate			<50>	<50>	<50>	<50>	
	adenoma	0	( 0%)	1	( 2%)	0	( 0%)
						0	( 0%)
mammary gl			<50>	<50>	<50>	<50>	
	fibroadenoma	1	( 2%)	1	( 2%)	0	( 0%)
						0	( 0%)
prep/cli gl			<50>	<50>	<50>	<50>	
	adenocarcinoma	2	( 4%)	2	( 4%)	0	( 0%)
						0	( 0%)
[Nervous system]							
brain			<50>	<50>	<50>	<50>	
	glioma	1	( 2%)	1	( 2%)	2	( 4%)
						1	( 2%)
	meningioma:malignant	1	( 2%)	0	( 0%)	0	( 0%)
						0	( 0%)
periph nerv			<50>	<50>	<50>	<50>	
	schwannoma:malignant	1	( 2%)	0	( 0%)	0	( 0%)
						0	( 0%)
[Special sense organs/appendage]							
Zymbal gl			<50>	<50>	<50>	<50>	
	squamous cell carcinoma	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



STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 5

Organ_____	Findings_____	Group Name No. of animals on Study	Control 50	200 ppm 50	400 ppm 50	800 ppm 50
<hr/>						
[Musculoskeletal system]						
bone			<50>	<50>	<50>	<50>
	osteosarcoma		0 ( 0%)	2 ( 4%)	1 ( 2%)	0 ( 0%)
[Body cavities]						
peritoneum			<50>	<50>	<50>	<50>
	mesothelioma		1 ( 2%)	1 ( 2%)	2 ( 4%)	1 ( 2%)
retroperit			<50>	<50>	<50>	<50>
	lipoma		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

(HPT085)

BAIS3

## APPENDIX L 2

HISTOLOGICAL FINDINGS: NEOPLASTIC LESIONS: SUMMARY, RAT: FEMALE

( 2-YEAR STUDY )

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 6

Organ	Findings	Group Name No. of animals on Study	Control 49	200 ppm 50	400 ppm 50	800 ppm 50
[Integumentary system/appandage]						
skin/app			<49>	<50>	<50>	<50>
	squamous cell papilloma		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
	keratoacanthoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
	basal cell carcinoma		1 ( 2%)	0 ( 0%)	0 ( 0%)	0 ( 0%)
subcutis			<49>	<50>	<50>	<50>
	fibroma		0 ( 0%)	1 ( 2%)	0 ( 0%)	1 ( 2%)
[Respiratory system]						
nasal cavit			<49>	<50>	<50>	<50>
	chondroma		1 ( 2%)	0 ( 0%)	0 ( 0%)	0 ( 0%)
lung			<49>	<50>	<50>	<50>
	bronchiolar-alveolar adenoma		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
	bronchiolar-alveolar carcinoma		0 ( 0%)	1 ( 2%)	1 ( 2%)	0 ( 0%)
[Hematopoietic system]						
spleen			<49>	<50>	<50>	<50>
	mononuclear cell leukemia		4 ( 8%)	5 ( 10%)	9 ( 18%)	4 ( 8%)
[Digestive system]						
large intes			<49>	<50>	<50>	<50>
	adenocarcinoma		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
liver			<49>	<50>	<50>	<50>
	hepatocellular adenoma		1 ( 2%)	1 ( 2%)	5 ( 10%)	16 ( 32%)

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 7

Organ	Findings	Group Name No. of animals on Study	Control 49	200 ppm 50	400 ppm 50	800 ppm 50
[Digestive system]						
liver			<49>	<50>	<50>	<50>
	cholangiocellular adenoma		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
	hepatocholangiocellular adenoma		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
	hepatocellular carcinoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	5 ( 10%)
pancreas			<49>	<50>	<50>	<50>
	islet cell adenoma		1 ( 2%)	0 ( 0%)	0 ( 0%)	0 ( 0%)
[Urinary system]						
kidney			<49>	<50>	<50>	<50>
	renal cell carcinoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
	nephroblastoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
urin bladd			<49>	<48>	<50>	<50>
	transitional cell papilloma		0 ( 0%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
[Endocrine system]						
pituitary			<49>	<50>	<50>	<50>
	adenoma		23 ( 47%)	20 ( 40%)	13 ( 26%)	4 ( 8%)
thyroid			<49>	<50>	<50>	<50>
	C-cell adenoma		7 ( 14%)	4 ( 8%)	2 ( 4%)	0 ( 0%)
	follicular adenoma		2 ( 4%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
	C-cell carcinoma		1 ( 2%)	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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 8

Organ_____	Findings_____	Group Name No. of animals on Study	Control 49	200 ppm 50	400 ppm 50	800 ppm 50
[Endocrine system]						
thyroid			<49>	<50>	<50>	<50>
	follicular adenocarcinoma	1 ( 2%)	0 ( 0%)	0 ( 0%)	0 ( 0%)	
parathyroid			<40>	<48>	<41>	<39>
	adenoma	1 ( 3%)	0 ( 0%)	0 ( 0%)	0 ( 0%)	
adrenal			<49>	<50>	<50>	<50>
	pheochromocytoma	0 ( 0%)	1 ( 2%)	1 ( 2%)	1 ( 2%)	
	ganglioneuroma	0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)	
	pheochromocytoma:malignant	1 ( 2%)	0 ( 0%)	1 ( 2%)	0 ( 0%)	
[Reproductive system]						
ovary			<49>	<50>	<50>	<50>
	granulosa-theca cell tumor	3 ( 6%)	0 ( 0%)	0 ( 0%)	0 ( 0%)	
uterus			<49>	<50>	<50>	<50>
	endometrial stromal polyp	3 ( 6%)	7 ( 14%)	11 ( 22%)	1 ( 2%)	
	endometrial stromal sarcoma	1 ( 2%)	1 ( 2%)	0 ( 0%)	0 ( 0%)	
mammary gl			<49>	<50>	<50>	<50>
	adenoma	0 ( 0%)	2 ( 4%)	0 ( 0%)	0 ( 0%)	
	fibroadenoma	7 ( 14%)	5 ( 10%)	0 ( 0%)	0 ( 0%)	
	adenocarcinoma	0 ( 0%)	2 ( 4%)	0 ( 0%)	0 ( 0%)	
prep/cli gl			<48>	<50>	<50>	<50>
	adenocarcinoma	0 ( 0%)	2 ( 4%)	0 ( 0%)	0 ( 0%)	

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 9

Organ	Findings	Group Name No. of animals on Study	Control 49	200 ppm 50	400 ppm 50	800 ppm 50
[Nervous system]						
brain	glioma		<49> 1 ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)
[Special sense organs/appendage]						
Zymbal gl	squamous cell carcinoma		<49> 1 ( 2%)	<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)

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

(HPT085)

BAIS3

APPENDIX M 1

NEOPLASTIC LESIONS - INCIDENCE AND STATISTICAL ANALYSIS, RAT: MALE

( 2-YEAR STUDY )

STUDY No. : 0296  
ANIMAL : RAT F344/DuCrj  
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 1

Group Name	Control	200 ppm	400 ppm	800 ppm
SITE : subcutis TUMOR : fibroma				
Tumor rate				
Overall rates(a)	4/50( 8.0)	7/50( 14.0)	1/50( 2.0)	2/50( 4.0)
Adjusted rates(b)	7.14	15.79	2.50	0.0
Terminal rates(c)	3/42( 7.1)	6/38( 15.8)	1/40( 2.5)	0/37( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.2410			
Prevalence method(d)	P = 0.9812			
Combined analysis(d)	P = 0.8988			
Cochran-Armitage test(e)	P = 0.1599			
Fisher Exact test(e)		P = 0.2623	P = 0.1811	P = 0.3389
SITE : lung TUMOR : bronchiolar-alveolar adenoma				
Tumor rate				
Overall rates(a)	3/50( 6.0)	2/50( 4.0)	1/50( 2.0)	1/50( 2.0)
Adjusted rates(b)	7.14	5.26	2.50	2.70
Terminal rates(c)	3/42( 7.1)	2/38( 5.3)	1/40( 2.5)	1/37( 2.7)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.8404			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.2689			
Fisher Exact test(e)		P = 0.5000	P = 0.3087	P = 0.3087
SITE : lung TUMOR : bronchiolar-alveolar adenoma,bronchiolar-alveolar carcinoma				
Tumor rate				
Overall rates(a)	4/50( 8.0)	2/50( 4.0)	1/50( 2.0)	1/50( 2.0)
Adjusted rates(b)	9.52	5.26	2.50	2.70
Terminal rates(c)	4/42( 9.5)	2/38( 5.3)	1/40( 2.5)	1/37( 2.7)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.9168			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.1432			
Fisher Exact test(e)		P = 0.3389	P = 0.1811	P = 0.1811



STUDY No. : 0296  
ANIMAL : RAT F344/DuCrj  
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 2

Group Name	Control	200 ppm	400 ppm	800 ppm
SITE : spleen TUMOR : mononuclear cell leukemia				
Tumor rate				
Overall rates(a)	3/50( 6.0)	2/50( 4.0)	3/50( 6.0)	4/49( 8.2)
Adjusted rates(b)	2.38	2.63	2.50	5.41
Terminal rates(c)	1/42( 2.4)	1/38( 2.6)	1/40( 2.5)	2/37( 5.4)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.3927			
Prevalence method(d)	P = 0.2204			
Combined analysis(d)	P = 0.2438			
Cochran-Armitage test(e)	P = 0.5264			
Fisher Exact test(e)		P = 0.5000	P = 0.3389	P = 0.4886
SITE : liver TUMOR : hepatocellular adenoma				
Tumor rate				
Overall rates(a)	1/50( 2.0)	3/50( 6.0)	13/50( 26.0)	20/50( 40.0)
Adjusted rates(b)	2.38	7.89	28.26	47.37
Terminal rates(c)	1/42( 2.4)	3/38( 7.9)	10/40( 25.0)	17/37( 45.9)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.1082			
Prevalence method(d)	P < 0.0001**			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.3087	P = 0.0004**	P < 0.0001**
SITE : liver TUMOR : hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	1/50( 2.0)	0/50( 0.0)	24/50( 48.0)
Adjusted rates(b)	0.0	2.63	0.0	56.76
Terminal rates(c)	0/42( 0.0)	1/38( 2.6)	0/40( 0.0)	21/37( 56.8)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0175* ?			
Prevalence method(d)	P < 0.0001**?			
Combined analysis(d)	P < 0.0001**?			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.5000	P = 0.5000	P < 0.0001**

STUDY No. : 0296  
ANIMAL : RAT F344/DuCrj  
SEX : MALE

# NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 3

Group Name	Control	200 ppm	400 ppm	800 ppm
SITE : liver TUMOR : hepatocellular adenoma,hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	1/50( 2.0)	4/50( 8.0)	13/50( 26.0)	33/50( 66.0)
Adjusted rates(b)	2.38	10.53	28.26	75.68
Terminal rates(c)	1/42( 2.4)	4/38( 10.5)	10/40( 25.0)	28/37( 75.7)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0041**?			
Prevalence method(d)	P < 0.0001**?			
Combined analysis(d)	P < 0.0001**?			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.1811	P = 0.0004**	P < 0.0001**
SITE : pancreas TUMOR : islet cell adenocarcinoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	3/50( 6.0)	0/50( 0.0)	0/50( 0.0)
Adjusted rates(b)	0.0	6.98	0.0	0.0
Terminal rates(c)	0/42( 0.0)	2/38( 5.3)	0/40( 0.0)	0/37( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.7851			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.3762			
Fisher Exact test(e)		P = 0.1212	P = 0.5000	P = 0.5000
SITE : pancreas TUMOR : islet cell adenoma,islet cell adenocarcinoma				
Tumor rate				
Overall rates(a)	1/50( 2.0)	3/50( 6.0)	2/50( 4.0)	1/50( 2.0)
Adjusted rates(b)	2.38	6.98	5.00	2.70
Terminal rates(c)	1/42( 2.4)	2/38( 5.3)	2/40( 5.0)	1/37( 2.7)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.5943			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.7450			
Fisher Exact test(e)		P = 0.3087	P = 0.5000	P = 0.2475

STUDY No. : 0296  
ANIMAL : RAT F344/DuCrj  
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 4

Group Name	Control	200 ppm	400 ppm	800 ppm
SITE : pituitary gland TUMOR : adenoma				
Tumor rate				
Overall rates(a)	9/50( 18.0)	17/50( 34.0)	4/50( 8.0)	3/50( 6.0)
Adjusted rates(b)	17.39	33.33	10.00	8.11
Terminal rates(c)	7/42( 16.7)	12/38( 31.6)	4/40( 10.0)	3/37( 8.1)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.8911			
Prevalence method(d)	P = 0.9906			
Combined analysis(d)	P = 0.9960			
Cochran-Armitage test(e)	P = 0.0075**			
Fisher Exact test(e)		P = 0.0548	P = 0.1168	P = 0.0606
SITE : pituitary gland TUMOR : adenoma,adenocarcinoma				
Tumor rate				
Overall rates(a)	9/50( 18.0)	17/50( 34.0)	5/50( 10.0)	3/50( 6.0)
Adjusted rates(b)	17.39	33.33	12.50	8.11
Terminal rates(c)	7/42( 16.7)	12/38( 31.6)	5/40( 12.5)	3/37( 8.1)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.8911			
Prevalence method(d)	P = 0.9887			
Combined analysis(d)	P = 0.9950			
Cochran-Armitage test(e)	P = 0.0091**			
Fisher Exact test(e)		P = 0.0548	P = 0.1940	P = 0.0606
SITE : thyroid TUMOR : C-cell adenoma				
Tumor rate				
Overall rates(a)	10/50( 20.0)	8/50( 16.0)	9/50( 18.0)	5/50( 10.0)
Adjusted rates(b)	23.81	20.00	21.95	13.51
Terminal rates(c)	10/42( 23.8)	7/38( 18.4)	8/40( 20.0)	5/37( 13.5)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.8938			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.1922			
Fisher Exact test(e)		P = 0.3976	P = 0.5000	P = 0.1312

STUDY No. : 0296  
ANIMAL : RAT F344/DuCrj  
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 5

Group Name	Control	200 ppm	400 ppm	800 ppm
SITE : thyroid TUMOR : C-cell adenoma,C-cell carcinoma				
Tumor rate				
Overall rates(a)	11/50( 22.0)	8/50( 16.0)	9/50( 18.0)	5/50( 10.0)
Adjusted rates(b)	26.19	20.00	21.95	13.51
Terminal rates(c)	11/42( 26.2)	7/38( 18.4)	8/40( 20.0)	5/37( 13.5)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.9294			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.1302			
Fisher Exact test(e)		P = 0.3055	P = 0.4016	P = 0.0857
SITE : thyroid TUMOR : follicular adenoma,follicular adenocarcinoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	3/50( 6.0)	2/50( 4.0)	0/50( 0.0)
Adjusted rates(b)	0.0	7.89	5.00	0.0
Terminal rates(c)	0/42( 0.0)	3/38( 7.9)	2/40( 5.0)	0/37( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.6577			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.5920			
Fisher Exact test(e)		P = 0.1212	P = 0.2475	P = 0.5000
SITE : adrenal gland TUMOR : pheochromocytoma				
Tumor rate				
Overall rates(a)	1/50( 2.0)	5/50( 10.0)	4/50( 8.0)	1/50( 2.0)
Adjusted rates(b)	2.38	13.16	6.98	2.22
Terminal rates(c)	1/42( 2.4)	5/38( 13.2)	2/40( 5.0)	0/37( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.3960			
Prevalence method(d)	P = 0.6671			
Combined analysis(d)	P = 0.6381			
Cochran-Armitage test(e)	P = 0.6370			
Fisher Exact test(e)		P = 0.1022	P = 0.1811	P = 0.2475

STUDY No. : 0296  
ANIMAL : RAT F344/DuCrj  
SEX : MALE

# NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 6

Group Name	Control	200 ppm	400 ppm	800 ppm
SITE : adrenal gland TUMOR : pheochromocytoma,pheochromocytoma:malignant				
Tumor rate				
Overall rates(a)	3/50( 6.0)	5/50( 10.0)	5/50( 10.0)	1/50( 2.0)
Adjusted rates(b)	4.76	13.16	9.30	2.22
Terminal rates(c)	2/42( 4.8)	5/38( 13.2)	3/40( 7.5)	0/37( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.7236			
Prevalence method(d)	P = 0.7658			
Combined analysis(d)	P = 0.8284			
Cochran-Armitage test(e)	P = 0.3027			
Fisher Exact test(e)		P = 0.3575	P = 0.3575	P = 0.3087
SITE : testis TUMOR : interstitial cell tumor				
Tumor rate				
Overall rates(a)	44/50( 88.0)	43/50( 86.0)	46/50( 92.0)	42/50( 84.0)
Adjusted rates(b)	93.33	93.33	97.73	95.00
Terminal rates(c)	39/42( 92.9)	35/38( 92.1)	39/40( 97.5)	35/37( 94.6)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.2823			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.6385			
Fisher Exact test(e)		P = 0.5000	P = 0.3703	P = 0.3871

(HPT360A)

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- (a): Number of tumor-bearing animals/number of animals examined at the site.  
(b): Kaplan-Meire estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.  
(c): Observed tumor incidence at terminal kill.  
(d): Beneath the control incidence are the P-values associated with the trend test.  
Standard method : Death analysis  
Prevalence method : Incidental tumor test  
Combined analysis : Death analysis + Incidental tumor test  
(e): The Cochran-Armitage and Fisher exact test compare directly the overall incidence rates.  
?: The conditional probabilities of the largest and smallest possible outcomes can not be estimated or this P-value is beyond the estimated P-value.  
----- : There is no data which should be statistical analysis.  
Significant difference : \* :  $P \leq 0.05$  \*\* :  $P \leq 0.01$

APPENDIX M 2

NEOPLASTIC LESIONS - INCIDENCE AND STATISTICAL ANALYSIS, RAT: FEMALE

( 2-YEAR STUDY )

STUDY No. : 0296  
ANIMAL : RAT F344/DuCrj  
SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 7

Group Name	Control	200 ppm	400 ppm	800 ppm
SITE : spleen TUMOR : mononuclear cell leukemia				
Tumor rate				
Overall rates(a)	4/49( 8.2)	5/50( 10.0)	9/50( 18.0)	4/50( 8.0)
Adjusted rates(b)	4.76	2.63	5.26	10.00
Terminal rates(c)	2/42( 4.8)	1/38( 2.6)	2/38( 5.3)	3/30( 10.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.5197			
Prevalence method(d)	P = 0.1387			
Combined analysis(d)	P = 0.2724			
Cochran-Armitage test(e)	P = 0.0626			
Fisher Exact test(e)		P = 0.4870	P = 0.1245	P = 0.3461
SITE : Liver TUMOR : hepatocellular adenoma				
Tumor rate				
Overall rates(a)	1/49( 2.0)	1/50( 2.0)	5/50( 10.0)	16/50( 32.0)
Adjusted rates(b)	2.38	2.50	13.16	53.33
Terminal rates(c)	1/42( 2.4)	0/38( 0.0)	5/38( 13.2)	16/30( 53.3)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P < 0.0001**?			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.2424	P = 0.1068	P < 0.0001**
SITE : Liver TUMOR : hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	0/49( 0.0)	0/50( 0.0)	0/50( 0.0)	5/50( 10.0)
Adjusted rates(b)	0.0	0.0	0.0	15.15
Terminal rates(c)	0/42( 0.0)	0/38( 0.0)	0/38( 0.0)	4/30( 13.3)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0001**?			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0006**			
Fisher Exact test(e)		P = 0.5000	P = 0.5000	P = 0.0296*

STUDY No. : 0296  
ANIMAL : RAT F344/DuCrj  
SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 8

Group Name	Control	200 ppm	400 ppm	800 ppm
SITE : liver TUMOR : hepatocellular adenoma,hepatocellular carcinoma				
Tumor rate				
Overall rates(a)	1/49( 2.0)	1/50( 2.0)	5/50( 10.0)	19/50( 38.0)
Adjusted rates(b)	2.38	2.50	13.16	60.00
Terminal rates(c)	1/42( 2.4)	0/38( 0.0)	5/38( 13.2)	18/30( 60.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P < 0.0001**?			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.2424	P = 0.1068	P < 0.0001**
SITE : pituitary gland TUMOR : adenoma				
Tumor rate				
Overall rates(a)	23/49( 46.9)	20/50( 40.0)	13/50( 26.0)	4/50( 8.0)
Adjusted rates(b)	45.45	37.21	26.32	10.00
Terminal rates(c)	18/42( 42.9)	12/38( 31.6)	10/38( 26.3)	3/30( 10.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.6171			
Prevalence method(d)	P = 1.0000			
Combined analysis(d)	P = 0.9999			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.3109	P = 0.0249*	P < 0.0001**
SITE : pituitary gland TUMOR : adenoma,adenocarcinoma				
Tumor rate				
Overall rates(a)	23/49( 46.9)	20/50( 40.0)	13/50( 26.0)	4/50( 8.0)
Adjusted rates(b)	45.45	37.21	26.32	10.00
Terminal rates(c)	18/42( 42.9)	12/38( 31.6)	10/38( 26.3)	3/30( 10.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.6171			
Prevalence method(d)	P = 1.0000			
Combined analysis(d)	P = 0.9999			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.3109	P = 0.0249*	P < 0.0001**



STUDY No. : 0296  
ANIMAL : RAT F344/DuCrj  
SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 9

Group Name	Control	200 ppm	400 ppm	800 ppm
SITE : thyroid TUMOR : C-cell adenoma				
Tumor rate				
Overall rates(a)	7/49( 14.3)	4/50( 8.0)	2/50( 4.0)	0/50( 0.0)
Adjusted rates(b)	15.22	9.52	5.26	0.0
Terminal rates(c)	6/42( 14.3)	3/38( 7.9)	2/38( 5.3)	0/30( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.9973			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0039**			
Fisher Exact test(e)		P = 0.2505	P = 0.0750	P = 0.0058**
SITE : thyroid TUMOR : C-cell adenoma,C-cell carcinoma				
Tumor rate				
Overall rates(a)	8/49( 16.3)	4/50( 8.0)	2/50( 4.0)	1/50( 2.0)
Adjusted rates(b)	17.39	9.52	5.26	3.33
Terminal rates(c)	7/42( 16.7)	3/38( 7.9)	2/38( 5.3)	1/30( 3.3)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.9911			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0090**			
Fisher Exact test(e)		P = 0.1685	P = 0.0426*	P = 0.0142*
SITE : thyroid TUMOR : follicular adenoma,follicular adenocarcinoma				
Tumor rate				
Overall rates(a)	3/49( 6.1)	1/50( 2.0)	0/50( 0.0)	0/50( 0.0)
Adjusted rates(b)	7.14	2.63	0.0	0.0
Terminal rates(c)	3/42( 7.1)	1/38( 2.6)	0/38( 0.0)	0/30( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.9841			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0391*			
Fisher Exact test(e)		P = 0.3010	P = 0.1175	P = 0.1175

STUDY No. : 0296  
ANIMAL : RAT F344/DuCrj  
SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 10

Group Name	Control	200 ppm	400 ppm	800 ppm
SITE : ovary TUMOR : granulosa-theca cell tumor				
Tumor rate				
Overall rates(a)	3/49( 6.1)	0/50( 0.0)	0/50( 0.0)	0/50( 0.0)
Adjusted rates(b)	7.14	0.0	0.0	0.0
Terminal rates(c)	3/42( 7.1)	0/38( 0.0)	0/38( 0.0)	0/30( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.9910			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0378*			
Fisher Exact test(e)		P = 0.1175	P = 0.1175	P = 0.1175
SITE : uterus TUMOR : endometrial stromal polyp				
Tumor rate				
Overall rates(a)	3/49( 6.1)	7/50( 14.0)	11/50( 22.0)	1/50( 2.0)
Adjusted rates(b)	7.14	15.79	27.50	3.33
Terminal rates(c)	3/42( 7.1)	6/38( 15.8)	10/38( 26.3)	1/30( 3.3)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.5553			
Prevalence method(d)	P = 0.5760			
Combined analysis(d)	P = 0.6115			
Cochran-Armitage test(e)	P = 0.3837			
Fisher Exact test(e)		P = 0.1672	P = 0.0223*	P = 0.3010
SITE : mammary gland TUMOR : fibroadenoma				
Tumor rate				
Overall rates(a)	7/49( 14.3)	5/50( 10.0)	0/50( 0.0)	0/50( 0.0)
Adjusted rates(b)	13.33	11.11	0.0	0.0
Terminal rates(c)	5/42( 11.9)	4/38( 10.5)	0/38( 0.0)	0/30( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.8966 ?			
Prevalence method(d)	P = 0.9991			
Combined analysis(d)	P = 0.9996			
Cochran-Armitage test(e)	P = 0.0012**			
Fisher Exact test(e)		P = 0.3654	P = 0.0058**	P = 0.0058**

STUDY No. : 0296  
ANIMAL : RAT F344/DuCrj  
SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 11

Group Name	Control	200 ppm	400 ppm	800 ppm
SITE : mammary gland TUMOR : adenoma, fibroadenoma				
Tumor rate				
Overall rates(a)	7/49( 14.3)	7/50( 14.0)	0/50( 0.0)	0/50( 0.0)
Adjusted rates(b)	13.33	15.79	0.0	0.0
Terminal rates(c)	5/42( 11.9)	6/38( 15.8)	0/38( 0.0)	0/30( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.8966 ?			
Prevalence method(d)	P = 0.9991			
Combined analysis(d)	P = 0.9996			
Cochran-Armitage test(e)	P = 0.0009**			
Fisher Exact test(e)		P = 0.3713	P = 0.0058**	P = 0.0058**
SITE : mammary gland TUMOR : adenoma, fibroadenoma, adenocarcinoma				
Tumor rate				
Overall rates(a)	7/49( 14.3)	9/50( 18.0)	0/50( 0.0)	0/50( 0.0)
Adjusted rates(b)	13.33	17.78	0.0	0.0
Terminal rates(c)	5/42( 11.9)	6/38( 15.8)	0/38( 0.0)	0/30( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.8571			
Prevalence method(d)	P = 0.9992			
Combined analysis(d)	P = 0.9996			
Cochran-Armitage test(e)	P = 0.0007**			
Fisher Exact test(e)		P = 0.4101	P = 0.0058**	P = 0.0058**

(HPT360A)

BAIS3

- (a): Number of tumor-bearing animals/number of animals examined at the site.  
(b): Kaplan-Meire estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.  
(c): Observed tumor incidence at terminal kill.  
(d): Beneath the control incidence are the P-values associated with the trend test.  
Standard method : Death analysis  
Prevalence method : Incidental tumor test  
Combined analysis : Death analysis + Incidental tumor test  
(e): The Cochran-Armitage and Fisher exact test compare directly the overall incidence rates.  
?: The conditional probabilities of the largest and smallest possible outcomes can not be estimated or this P-value is beyond the estimated P-value.  
----- : There is no data which should be statistical analysis.  
Significant difference : \* :  $P \leq 0.05$  \*\* :  $P \leq 0.01$

APPENDIX N 1

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 1

Group Name		Control	200 ppm	400 ppm	800 ppm
No. of Animals on Study		50	50	50	50
Organ	Findings				
[Respiratory system]					
Lung		<50>	<50>	<50>	<50>
	Leukemic cell infiltration	2	1	3	3
	metastasis:liver tumor	0	0	2	1
	metastasis:bone tumor	0	1	0	0
	metastasis:skin/appendage tumor	0	1	0	0
[Hematopoietic system]					
bone marrow		<50>	<50>	<50>	<50>
	Leukemic cell infiltration	3	1	3	2
	metastasis:liver tumor	0	0	1	0
Lymph node		<50>	<50>	<50>	<50>
	Leukemic cell infiltration	1	0	0	1
	metastasis:liver tumor	0	0	1	0
	metastasis:thyroid tumor	1	0	0	0
spleen		<50>	<50>	<50>	<48>
	metastasis:liver tumor	0	0	2	0
[Circulatory system]					
heart		<50>	<50>	<50>	<50>
	metastasis:liver tumor	0	0	0	1
[Digestive system]					
liver		<50>	<50>	<50>	<50>
	Leukemic cell infiltration	2	1	3	2
< a >	a : Number of animals examined at the site				
b	b : Number of animals with lesion				

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 2

Group Name		Control	200 ppm	400 ppm	800 ppm
No. of Animals on Study		50	50	50	50
Organ	Findings				
[Digestive system]					
liver		<50>	<50>	<50>	<50>
	metastasis:spleen tumor	0	0	0	1
pancreas		<50>	<50>	<50>	<50>
	leukemic cell infiltration	1	0	0	0
[Urinary system]					
kidney		<50>	<50>	<50>	<50>
	leukemic cell infiltration	1	0	0	0
[Endocrine system]					
adrenal		<50>	<50>	<50>	<50>
	leukemic cell infiltration	0	0	1	0
[Nervous system]					
brain		<50>	<50>	<50>	<50>
	leukemic cell infiltration	1	0	0	1
[Special sense organs/appendage]					
eye		<50>	<50>	<50>	<50>
	leukemic cell infiltration	1	0	0	0
[Musculoskeletal system]					
muscle		<50>	<50>	<50>	<50>
	metastasis:peripheral nerve tumor	1	0	0	0

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

## APPENDIX N 2

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 1

Group Name		Control	200 ppm	400 ppm	800 ppm
No. of Animals on Study		8	12	10	13
Organ	Findings				
[Respiratory system]					
lung		< 8>	<12>	<10>	<13>
	leukemic cell infiltration	2	1	2	2
	metastasis:liver tumor	0	0	2	0
	metastasis:skin/appendage tumor	0	1	0	0
[Hematopoietic system]					
bone marrow		< 8>	<12>	<10>	<13>
	leukemic cell infiltration	2	1	2	2
	metastasis:liver tumor	0	0	1	0
lymph node		< 8>	<12>	<10>	<13>
	leukemic cell infiltration	1	0	0	1
	metastasis:liver tumor	0	0	1	0
spleen		< 8>	<12>	<10>	<12>
	metastasis:liver tumor	0	0	2	0
[Circulatory system]					
heart		< 8>	<12>	<10>	<13>
	metastasis:lung tumor	0	0	0	1
[Digestive system]					
liver		< 8>	<12>	<10>	<13>
	leukemic cell infiltration	2	1	2	2
	metastasis:spleen tumor	0	0	0	1
< a >	a : Number of animals examined at the site				
b	b : Number of animals with lesion				



STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 2

Organ	Findings	Group Name No. of Animals on Study	Control 8	200 ppm 12	400 ppm 10	800 ppm 13
[Digestive system]						
pancreas	leukemic cell infiltration		< 8> 1	<12> 0	<10> 0	<13> 0
[Urinary system]						
kidney	leukemic cell infiltration		< 8> 1	<12> 0	<10> 0	<13> 0
[Endocrine system]						
adrenal	leukemic cell infiltration		< 8> 0	<12> 0	<10> 1	<13> 0
[Nervous system]						
brain	leukemic cell infiltration		< 8> 1	<12> 0	<10> 0	<13> 1
[Special sense organs/appendage]						
eye	leukemic cell infiltration		< 8> 1	<12> 0	<10> 0	<13> 0
[Musculoskeletal system]						
muscle	metastasis:peripheral nerve tumor		< 8> 1	<12> 0	<10> 0	<13> 0

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

## APPENDIX N 3

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 1

		Group Name	Control	200 ppm	400 ppm	800 ppm
		No. of Animals on Study	42	38	40	37
Organ	Findings					
[Respiratory system]						
Lung			<42>	<38>	<40>	<37>
	leukemic cell infiltration		0	0	1	1
	metastasis:liver tumor		0	0	0	1
	metastasis:bone tumor		0	1	0	0
[Hematopoietic system]						
bone marrow			<42>	<38>	<40>	<37>
	leukemic cell infiltration		1	0	1	0
Lymph node			<42>	<38>	<40>	<37>
	metastasis:thyroid tumor		1	0	0	0
[Digestive system]						
Liver			<42>	<38>	<40>	<37>
	leukemic cell infiltration		0	0	1	0
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					

(JPT150)

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APPENDIX N 4

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 3

Organ	Findings	Group Name No. of Animals on Study	Control 49	200 ppm 50	400 ppm 50	800 ppm 50
[Respiratory system]						
larynx			<49>	<50>	<50>	<50>
	metastasis:thyroid tumor		0	0	0	1
lung			<49>	<50>	<50>	<50>
	leukemic cell infiltration		4	5	6	4
	metastasis:uterus tumor		0	1	0	0
[Hematopoietic system]						
bone marrow			<49>	<50>	<50>	<50>
	leukemic cell infiltration		2	3	7	2
lymph node			<49>	<50>	<50>	<50>
	leukemic cell infiltration		0	2	1	0
	metastasis:kidney tumor		0	0	0	1
thymus			<49>	<50>	<50>	<50>
	leukemic cell infiltration		0	0	1	0
	metastasis:thyroid tumor		0	0	0	1
[Circulatory system]						
heart			<49>	<50>	<50>	<50>
	leukemic cell infiltration		0	2	1	0
[Digestive system]						
salivary gl			<49>	<50>	<50>	<50>
	leukemic cell infiltration		0	0	1	0

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 4

Group Name		Control	200 ppm	400 ppm	800 ppm
No. of Animals on Study		49	50	50	50
Organ	Findings				
[Digestive system]					
liver	leukemic cell infiltration	<49> 2	<50> 5	<50> 7	<50> 3
	metastasis:uterus tumor	0	1	0	0
pancreas	leukemic cell infiltration	<49> 1	<50> 0	<50> 1	<50> 0
	metastasis:uterus tumor	0	1	0	0
[Urinary system]					
kidney	leukemic cell infiltration	<49> 0	<50> 1	<50> 1	<50> 0
[Endocrine system]					
pituitary	leukemic cell infiltration	<49> 0	<50> 0	<50> 1	<50> 0
thyroid	leukemic cell infiltration	<49> 0	<50> 0	<50> 1	<50> 0
adrenal	leukemic cell infiltration	<49> 1	<50> 2	<50> 2	<50> 1
[Reproductive system]					
ovary	leukemic cell infiltration	<49> 0	<50> 0	<50> 2	<50> 0
uterus	leukemic cell infiltration	<49> 0	<50> 0	<50> 1	<50> 0

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 5

		Group Name	Control	200 ppm	400 ppm	800 ppm
		No. of Animals on Study	49	50	50	50
Organ	Findings					
[Reproductive system]						
vagina			<49>	<50>	<50>	<50>
	leukemic cell infiltration		0	0	1	0
[Nervous system]						
brain			<49>	<50>	<50>	<50>
	leukemic cell infiltration		0	1	2	0
	metastasis:zymbal gland tumor		1	0	0	0
spinal cord			<49>	<50>	<50>	<50>
	leukemic cell infiltration		0	1	2	0
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					

(JPT150)

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APPENDIX N 5

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



STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 3

Group Name		Control	200 ppm	400 ppm	800 ppm
No. of Animals on Study		7	12	12	20
Organ	Findings				
[Respiratory system]					
lung		< 7>	<12>	<12>	<20>
	leukemic cell infiltration	2	4	5	1
	metastasis:uterus tumor	0	1	0	0
[Hematopoietic system]					
bone marrow		< 7>	<12>	<12>	<20>
	leukemic cell infiltration	1	3	6	0
lymph node		< 7>	<12>	<12>	<20>
	leukemic cell infiltration	0	1	0	0
	metastasis:kidney tumor	0	0	0	1
thymus		< 7>	<12>	<12>	<20>
	leukemic cell infiltration	0	0	1	0
[Circulatory system]					
heart		< 7>	<12>	<12>	<20>
	leukemic cell infiltration	0	2	1	0
[Digestive system]					
liver		< 7>	<12>	<12>	<20>
	leukemic cell infiltration	2	4	5	1
	metastasis:uterus tumor	0	1	0	0
pancreas		< 7>	<12>	<12>	<20>
	metastasis:uterus tumor	0	1	0	0

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 4

Organ	Findings	Group Name No. of Animals on Study	Control 7	200 ppm 12	400 ppm 12	800 ppm 20
[Urinary system]						
kidney			< 7>	<12>	<12>	<20>
	leukemic cell infiltration		0	1	0	0
[Endocrine system]						
pituitary			< 7>	<12>	<12>	<20>
	leukemic cell infiltration		0	0	1	0
adrenal			< 7>	<12>	<12>	<20>
	leukemic cell infiltration		1	2	2	0
[Reproductive system]						
ovary			< 7>	<12>	<12>	<20>
	leukemic cell infiltration		0	0	1	0
[Nervous system]						
brain			< 7>	<12>	<12>	<20>
	leukemic cell infiltration		0	1	2	0
	metastasis:zymbal gland tumor		1	0	0	0
spinal cord			< 7>	<12>	<12>	<20>
	leukemic cell infiltration		0	1	2	0

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

APPENDIX N 6

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

STUDY NO. : 0296  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 2

Organ_____ Findings_____		Group Name No. of Animals on Study	Control 42	200 ppm 38	400 ppm 38	800 ppm 30
[Respiratory system]						
Larynx			<42>	<38>	<38>	<30>
	metastasis:thyroid tumor		0	0	0	1
lung			<42>	<38>	<38>	<30>
	leukemic cell infiltration		2	1	1	3
[Hematopoietic system]						
bone marrow			<42>	<38>	<38>	<30>
	leukemic cell infiltration		1	0	1	2
Lymph node			<42>	<38>	<38>	<30>
	leukemic cell infiltration		0	1	1	0
thymus			<42>	<38>	<38>	<30>
	metastasis:thyroid tumor		0	0	0	1
[Digestive system]						
salivary gl			<42>	<38>	<38>	<30>
	leukemic cell infiltration		0	0	1	0
liver			<42>	<38>	<38>	<30>
	leukemic cell infiltration		0	1	2	2
pancreas			<42>	<38>	<38>	<30>
	leukemic cell infiltration		1	0	1	0
[Urinary system]						
kidney			<42>	<38>	<38>	<30>
	leukemic cell infiltration		0	0	1	0

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

STUDY NO. : 0296  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 3

		Group Name	Control	200 ppm	400 ppm	800 ppm
		No. of Animals on Study	42	38	38	30
Organ	Findings					
[Endocrine system]						
thyroid			<42>	<38>	<38>	<30>
	leukemic cell infiltration		0	0	1	0
adrenal			<42>	<38>	<38>	<30>
	leukemic cell infiltration		0	0	0	1
[Reproductive system]						
ovary			<42>	<38>	<38>	<30>
	leukemic cell infiltration		0	0	1	0
uterus			<42>	<38>	<38>	<30>
	leukemic cell infiltration		0	0	1	0
vagina			<42>	<38>	<38>	<30>
	leukemic cell infiltration		0	0	1	0
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					

(JPT150)

BAIS3

## APPENDIX O 1

### IDENTITY OF *N,N*-DIMETHYLFORMAMIDE IN THE 2-YEAR INHALATION STUDY

IDENTITY OF *N,N*-DIMETHYLFORMAMIDE THE 2-YEAR INHALATION STUDYTest Substance : *N,N*-Dimethylformamide (Wako Pure Chemical Industries, LTD.)

A. Lot No. : CAL4288

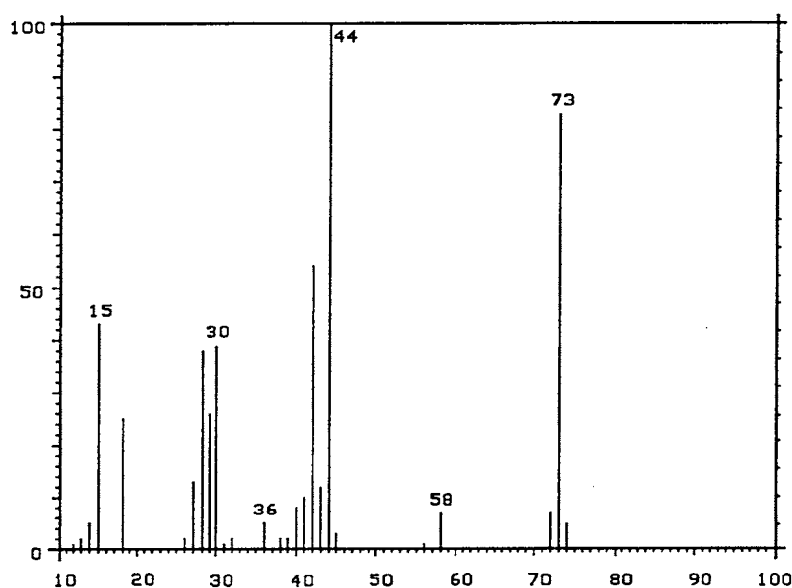
## 1. Spectral data

Mass Spectrometry

Instrument : Hitachi M-80B Mass Spectrometer

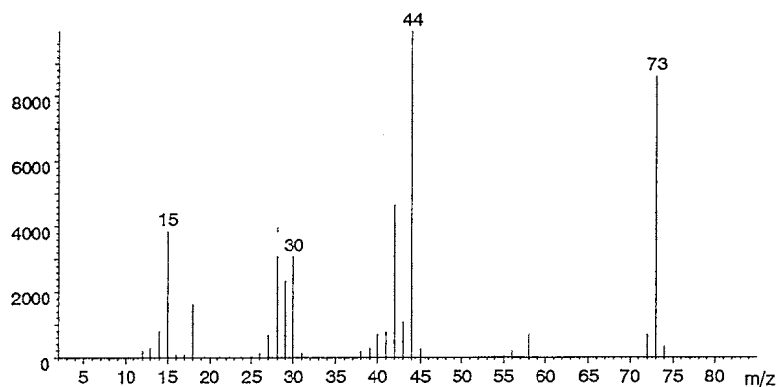
Ionization : EI(Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance

m/z

Mass Spectrum of *N,N*-dimethylformamide (Literature data\*)

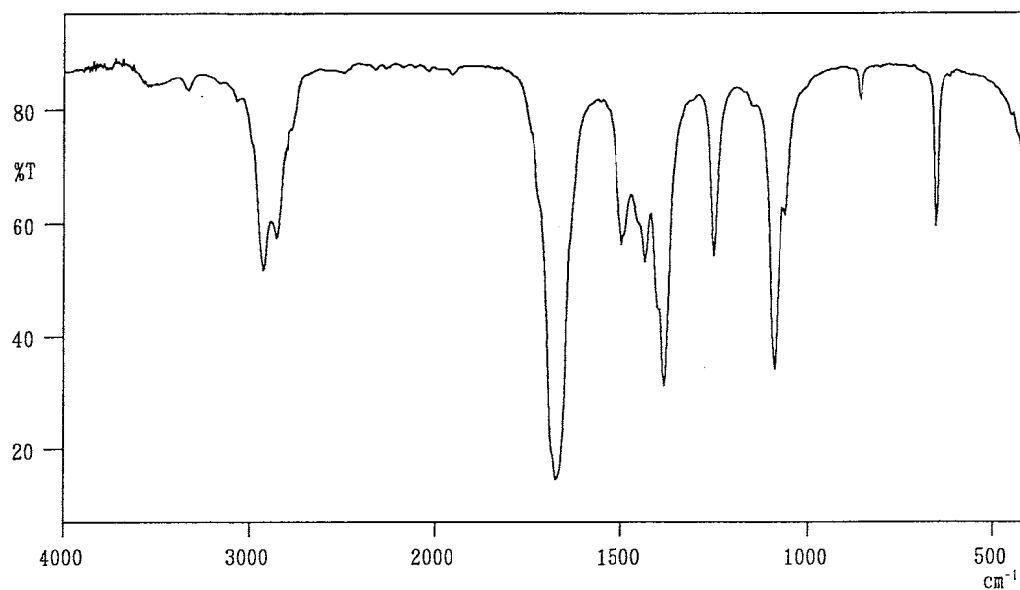
Results: The mass spectrum was consistent with literature spectrum.

\*Wiley 138K Mass Spectral Data Base Entry Number 1553(1990)  
John Wiley and Sons Inc., U.K.

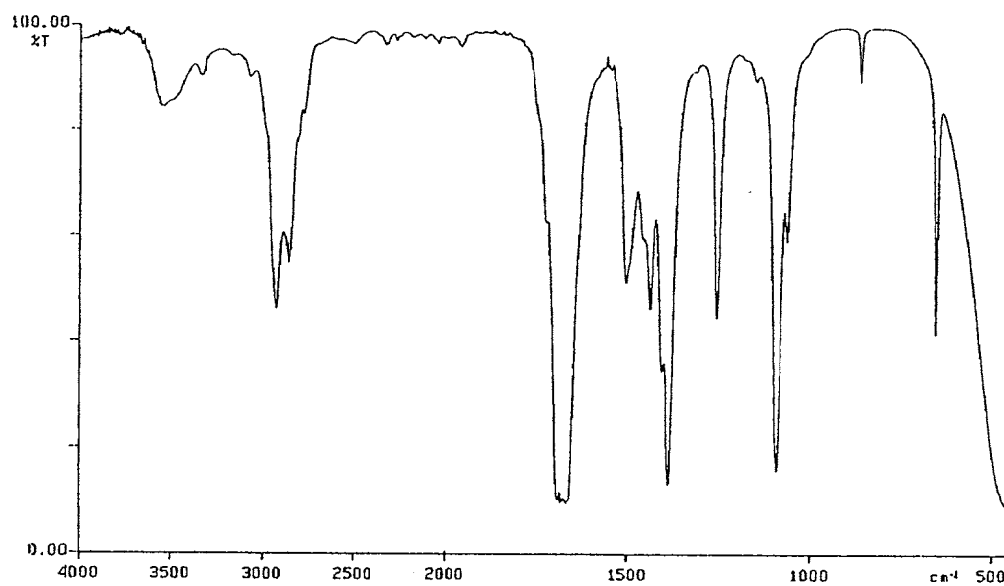
Infrared Spectrometry

Instrument : Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell : KBr



Infrared Spectrum of Test Substance



Infrared Spectrum of *N,N*-dimethylformamide (Literature data\*)

\*Performed by Wako Pure Chemical Industries, LTD.

Results: The infrared spectrum was consistent with literature spectrum.

2. Conclusions: The test substance was identified as *N,N*-dimethylformamide, by the mass spectrum and the infrared spectrum.



B. Lot No. : SKH4945

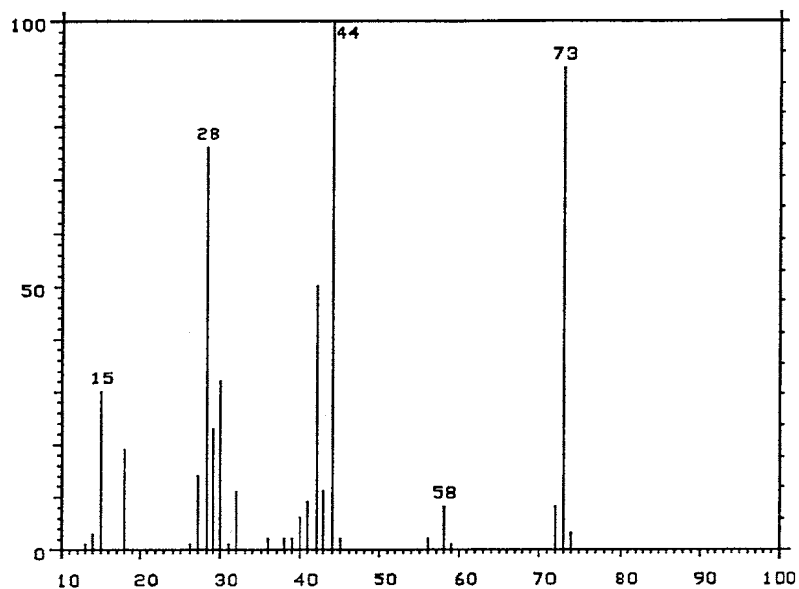
1. Spectral data

Mass Spectrometry

Instrument : Hitachi M-80B Mass Spectrometer

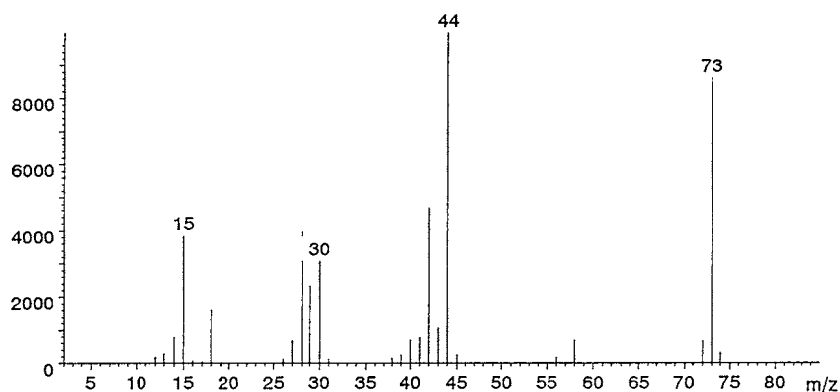
Ionization : EI(Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance

m/z



Mass Spectrum of *N,N*-dimethylformamide (Literature data\*)

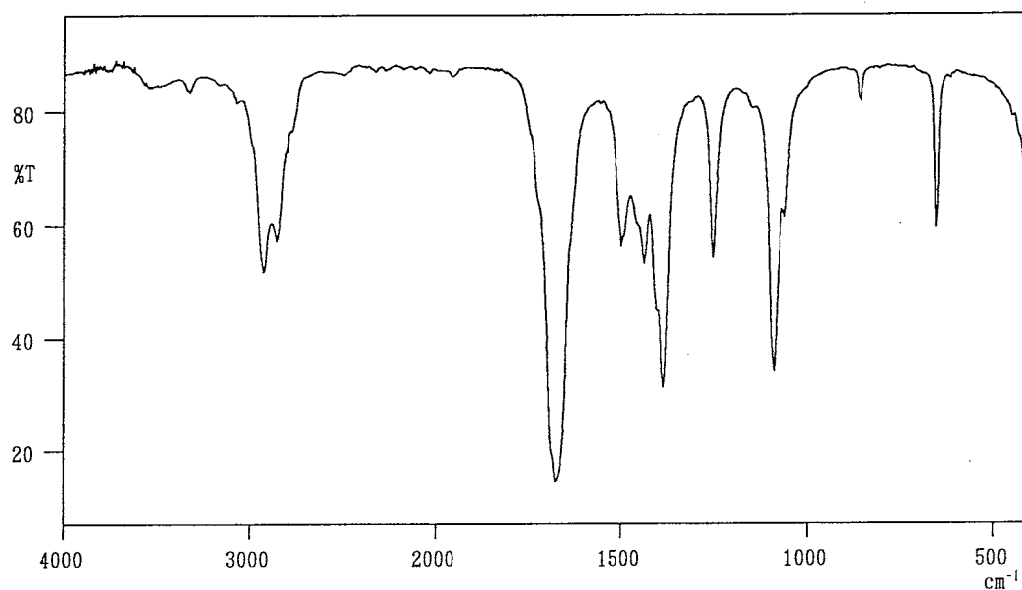
Results: The mass spectrum was consistent with literature spectrum.

\*Wiley 138K Mass Spectral Data Base Entry Number 1553(1990)  
John Wiley and Sons Inc.,U.K.

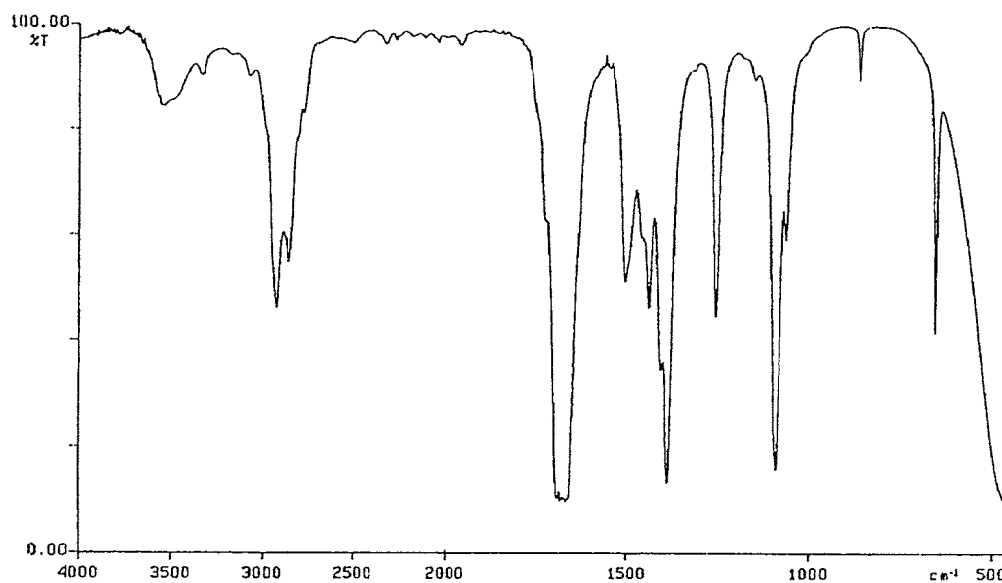
Infrared Spectrometry

Instrument : Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell : KBr



Infrared Spectrum of Test Substance



Infrared Spectrum of *N,N*-dimethylformamide (Literature data\*)

\*Performed by Wako Pure Chemical Industries, LTD.

Results: The infrared spectrum was consistent with literature spectrum.

2. Conclusions: The test substance was identified as *N,N*-dimethylformamide, by the mass spectrum and the infrared spectrum.

C. Lot No. : LEK4984

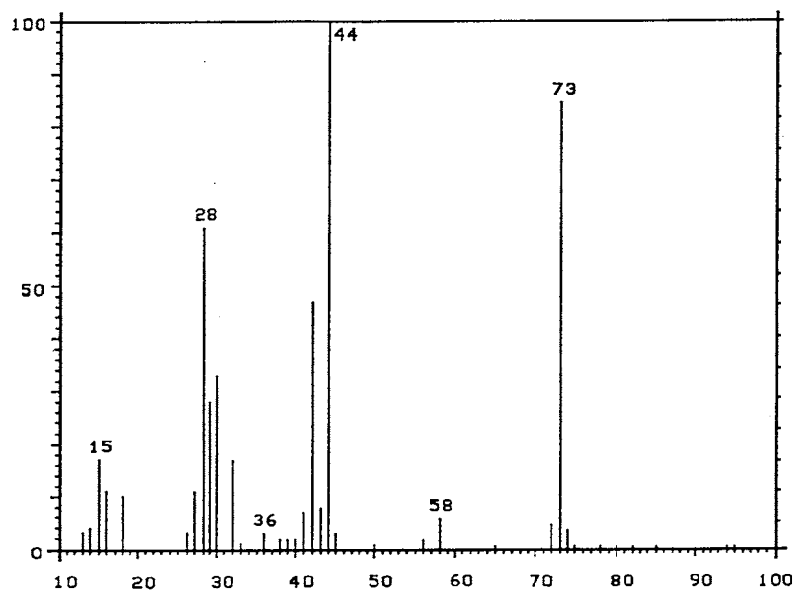
1. Spectral data

Mass Spectrometry

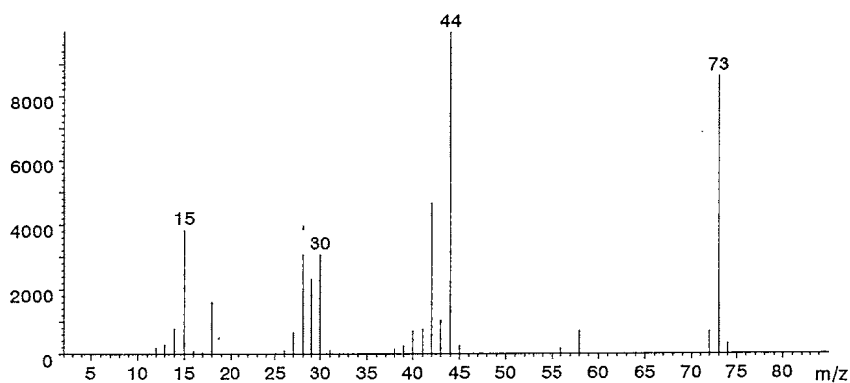
Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI(Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance m/z



Mass Spectrum of *N,N*-dimethylformamide (Literature data\*)

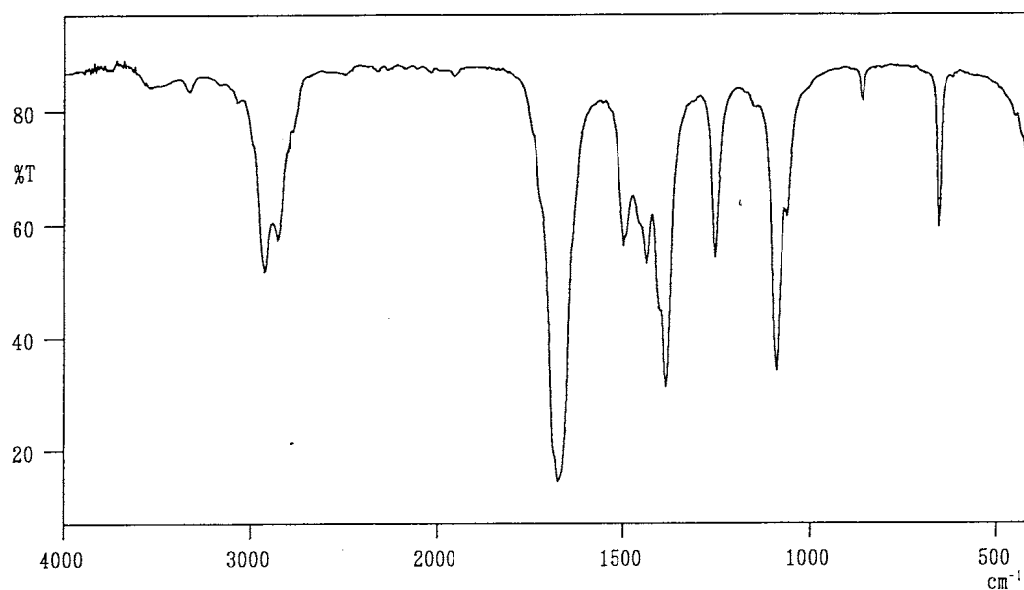
Results: The mass spectrum was consistent with literature spectrum.

\*Wiley 138K Mass Spectral Data Base Entry Number 1553(1990)  
John Wiley and Sons Inc.,U.K.

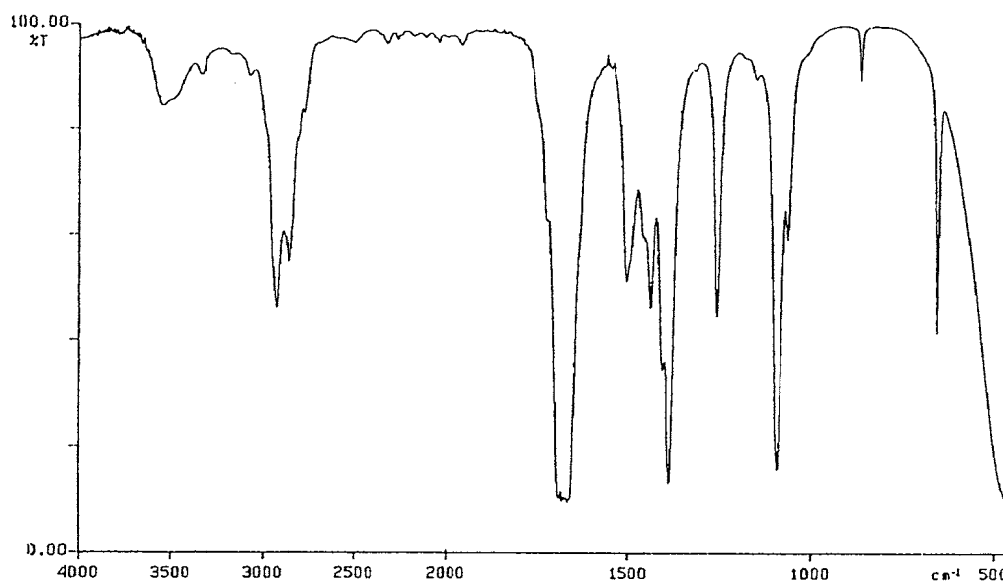
Infrared Spectrometry

Instrument : Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell : KBr



Infrared Spectrum of Test Substance



Infrared Spectrum of *N,N*-dimethylformamide (Literature data\*)

\*Performed by Wako Pure Chemical Industries, LTD.

Results: The infrared spectrum was consistent with literature spectrum.

2. Conclusions: The test substance was identified as *N,N*-dimethylformamide, by the mass spectrum and the infrared spectrum.

D. Lot No. : WTL5167

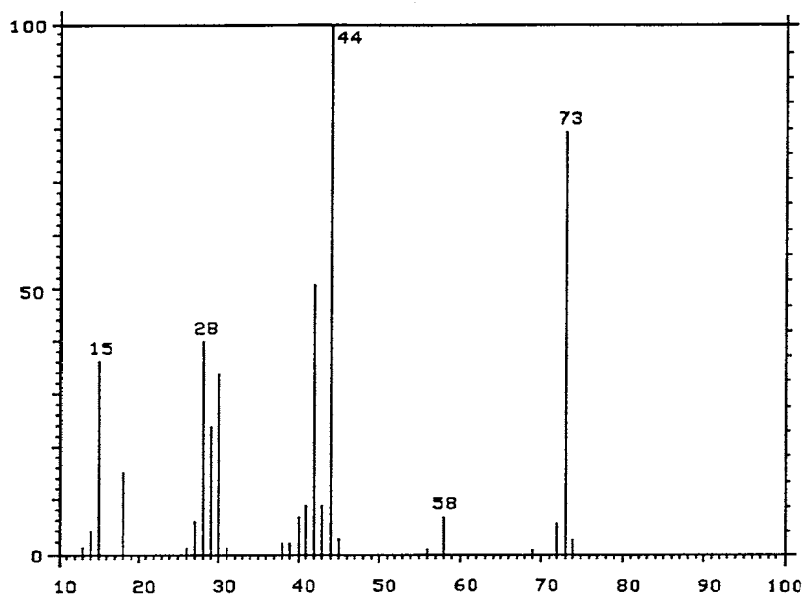
1. Spectral data

Mass Spectrometry

Instrument : Hitachi M-80B Mass Spectrometer

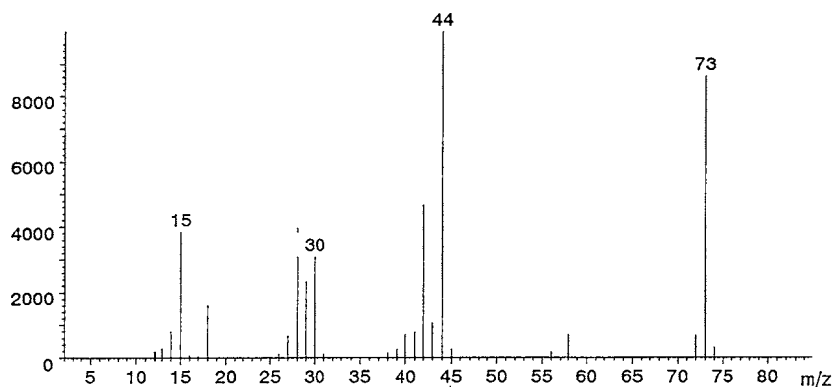
Ionization : EI(Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance

m/z



Mass Spectrum of *N,N*-dimethylformamide (Literature data\*)

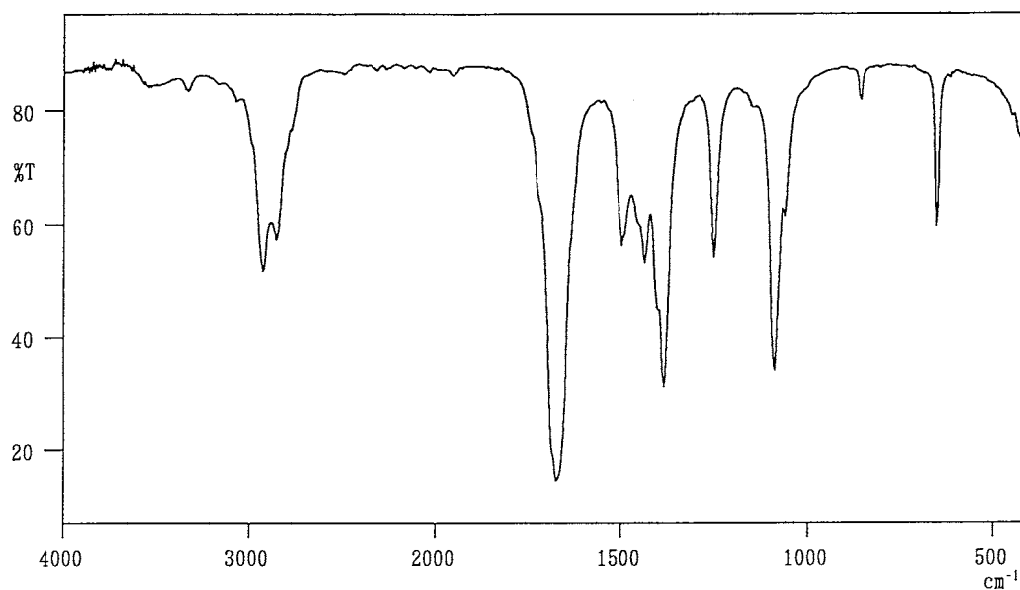
Results: The mass spectrum was consistent with literature spectrum.

\*Wiley 138K Mass Spectral Data Base Entry Number 1553(1990)  
John Wiley and Sons Inc.,U.K.

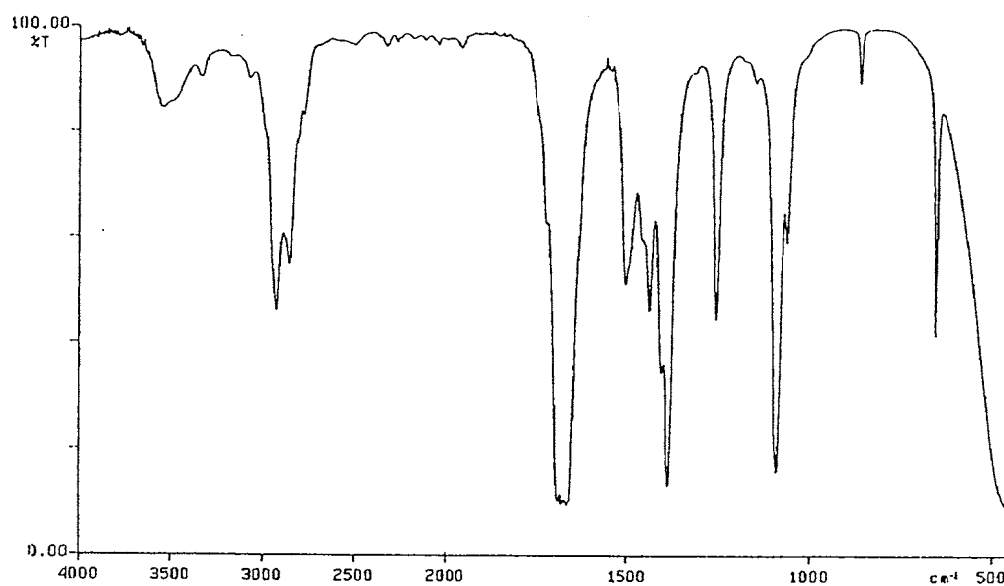
Infrared Spectrometry

Instrument : Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell : KBr



Infrared Spectrum of Test Substance



Infrared Spectrum of *N,N*-dimethylformamide (Literature data\*)

\*Performed by Wako Pure Chemical Industries, LTD.

Results: The infrared spectrum was consistent with literature spectrum.

2. Conclusions: The test substance was identified as *N,N*-dimethylformamide, by the mass spectrum and the infrared spectrum.

## APPENDIX O 2

### STABILITY OF *N,N*-DIMETHYLFORMAMIDE IN THE 2-YEAR INHALATION STUDY

STABILITY OF *N,N*-DIMETHYLFORMAMIDE IN THE 2-YEAR INHALATION STUDYTest Substance : *N,N*-Dimethylformamide (Wako Pure Chemical Industries, LTD.)

A. Lot No. : CAL4288

1. Sample: This lot was used from 1995.10.23 to 1995.11.13. Test substance was stored at room temperature .

## 2. Gas Chromatography

Instrument : Hewlett Packard 5890A  
Column : Hewlett Packard INNOWax(0.2mm  $\phi$   $\times$  50m)  
Column Temperature : 150°C  
Flow Rate : 1 ml/min  
Detector : FID(Flame Ionization Detector)  
Injection Volume : 1  $\mu$ l

Results : Gas chromatography indicated one major peak(peak No.1) analyzed at 1995.10.20 and one major peak(peak No.1) analyzed at 1995.11.13. No new trace impurity peak in the test substance analyzed at 1995.11.13 was detected.

Date (date analyzed)	Peak No.	Retention Time(min)	AREA(%)
1995.10.20	1	6.013	100
1995.11.13	1	6.012	100

3. Conclusions: The test substance was stable for about 3 weeks in the dark at room temperature.



B. Lot No. : SKH4945

1.Sample: This lot was used from 1995.11.14 to 1996.10.30. Test substance was stored at room temperature .

2. Gas Chromatography

Instrument : Hewlett Packard 5890A  
Column : Hewlett Packard INNOWax(0.2mm  $\phi$   $\times$  50m)  
Column Temperature : 150°C  
Flow Rate : 1 ml/min  
Detector : FID(Flame Ionization Detector)  
Injection Volume : 1  $\mu$ l

Results : Gas chromatography indicated one major peak(peak No.1) analyzed at 1995.11.13 and one major peak(peak No.1) analyzed at 1996.10.30. No new trace impurity peak in the test substance analyzed at 1996.10.30 was detected.

Date (date analyzed)	Peak No.	Retention Time(min)	AREA(%)
1995.11.13	1	6.012	100
1996.10.30	1	6.013	100

3. Conclusions: The test substance was stable for about 1 year in the dark at room temperature.

C. Lot No. : LEK4984

1.Sample: This lot was used from 1996.10.31 to 1997.10.22. Test substance was stored at room temperature .

2. Gas Chromatography

Instrument : Hewlett Packard 5890A  
Column : Hewlett Packard INNOWax(0.2mm  $\phi$   $\times$  50m)  
Column Temperature : 150°C  
Flow Rate : 1 ml/min  
Detector : FID(Flame Ionization Detector)  
Injection Volume : 1  $\mu$ l

Results : Gas chromatography indicated one major peak(peak No.1) analyzed at 1996.10.29 and one major peak(peak No.1) analyzed at 1997.10.23. No new trace impurity peak in the test substance analyzed at 1997.10.23 was detected.

Date (date analyzed)	Peak No.	Retention Time(min)	AREA(%)
1996.10.29	1	6.012	100
1997.10.23	1	6.01	100

3. Conclusions: The test substance was stable for about 1 year in the dark at room temperature.

D. Lot No. : WTL5167

1.Sample: This lot was used from 1997.10.23 to 1997.10.17. Test substance was stored at room temperature .

2. Gas Chromatography

Instrument : Hewlett Packard 5890A  
Column : Hewlett Packard INNOWax(0.2mm  $\phi$   $\times$  50m)  
Column Temperature : 150°C  
Flow Rate : 1 ml/min  
Detector : FID(Flame Ionization Detector)  
Injection Volume : 1  $\mu$ l

Results : Gas chromatography indicated one major peak(peak No.1) analyzed at 1997.10.21 and one major peak(peak No.1) analyzed at 1997.11.18. No new trace impurity peak in the test substance analyzed at 1997.11.18 was detected.

Date (date analyzed)	Peak No.	Retention Time(min)	AREA(%)
1997.10.21	1	6.012	100
1997.11.18	1	6.008	100

3. Conclusions: The test substance was stable for about 1 months in the dark at room temperature.

APPENDIX P 1

CONCENTRATION OF *N,N*-DIMETHYLFORMAMIDE IN INHALATION CHAMBER OF THE  
2-YEAR INHALATION STUDY

CONCENTRATION OF *N,N*-DIMETHYLFORMAMIDE IN THE INHALATION CHAMBER  
OF THE 2-YEAR INHALATION STUDY

Group Name	Concentration (ppm)
	Mean $\pm$ S.D.
Control	0.0 $\pm$ 0.0
200ppm	200.8 $\pm$ 4.9
400ppm	399.9 $\pm$ 12.5
800ppm	800.3 $\pm$ 26.1

APPENDIX P 2

ENVIRONMENTAL CONCENTRATION OF INHALATION CHAMBER IN THE 2-YEAR  
INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE

Group Name	Temperature(°C) Mean ± S.D.	Humidity(%) Mean ± S.D.	Ventilation Rate(L/min) Mean ± S.D.	Air Changes(time/h) Mean
Control	22.5 ± 0.4	55.0 ± 1.1	1537.0 ± 23.6 (762.4 ± 4.8)	12.1 (6.0)
200ppm	22.6 ± 0.4	51.5 ± 3.1	1527.6 ± 22.4 (763.4 ± 4.5)	12.1 (6.0)
800ppm	22.5 ± 0.4	51.9 ± 3.0	1539.4 ± 22.7 (764.9 ± 4.9)	12.2 (6.0)
400ppm	22.5 ± 0.4	52.7 ± 3.5	1537.0 ± 22.9 (763.8 ± 5.1)	12.1 (6.0)

( ):during exposure

## APPENDIX Q 1

### METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE



METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS  
IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE

Item	Method
<b>Hematology</b>	
Red blood cell (RBC)	Light scattering method <sup>1)</sup>
Hemoglobin (Hgb)	Cyanmethemoglobin method <sup>1)</sup>
Hematocrit (Hct)	Calculated as $RBC \times MCV/10$ <sup>1)</sup>
Mean corpuscular volume (MCV)	Light scattering method <sup>1)</sup>
Mean corpuscular hemoglobin (MCH)	Calculated as $Hgb/RBC \times 10$ <sup>1)</sup>
Mean corpuscular hemoglobin concentration (MCHC)	Calculated as $Hgb/Hct \times 100$ <sup>1)</sup>
Platelet	Light scattering method <sup>1)</sup>
White blood cell (WBC)	Light scattering method <sup>1)</sup>
Differential WBC	Pattern recognition method <sup>2)</sup> (May-Grunwald-Giemsa staining)
<b>Biochemistry</b>	
Total protein (TP)	Biuret method <sup>3)</sup>
Albumin (Alb)	BCG method <sup>3)</sup>
A/G ratio	Calculated as $Alb/(TP - Alb)$ <sup>3)</sup>
T-bilirubin	Alkaline azobilirubin method <sup>3)</sup>
Glucose	GlcK • G-6-PDH method <sup>3)</sup>
T-cholesterol	CE • COD • POD method <sup>3)</sup>
Triglyceride	LPL • GK • GPO • POD method <sup>3)</sup>
Phospholipid	PLD • ChOD • POD method <sup>3)</sup>
Glutamic oxaloacetic transaminase (GOT)	JSCC method <sup>3)</sup>
Glutamic pyruvic transaminase (GPT)	JSCC method <sup>3)</sup>
Lactate dehydrogenase (LDH)	SFBC method <sup>3)</sup>
Alkaline phosphatase (ALP)	GSCC method <sup>3)</sup>
$\gamma$ -Glutamyl transpeptidase ( $\gamma$ -GTP)	L- $\gamma$ -Glutamyl-p-nitroanilide method <sup>3)</sup>
Creatine phosphokinase (CPK)	JSCC method <sup>3)</sup>
Urea nitrogen	Urease • GLDH method <sup>3)</sup>
Creatinine	Jaffe method <sup>3)</sup>
Sodium	Ion selective electrode method <sup>3)</sup>
Potassium	Ion selective electrode method <sup>3)</sup>
Chloride	Ion selective electrode method <sup>3)</sup>
Calcium	OCPC method <sup>3)</sup>
Inorganic phosphorus	PNP • XOD • POD method <sup>3)</sup>
<b>Urinalysis</b>	
PH, Protein, Glucose, Ketone body, Bilirubin, Occult Blood, Urobilinogen	Urinalysis reagent paper method <sup>4)</sup>

1) Automatic blood cell analyzer (Technicon H-1 : Bayer)

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

3) Automatic analyzer (Hitachi 7070 : Hitachi, Ltd.)

4) Ames reagent strips for urinalysis (Multistix : Bayer Corporation)

## APPENDIX Q 2

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY  
IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY  
IN THE 2-YEAR INHALATION STUDY OF *N,N*-DIMETHYLFORMAMIDE

Item	Unit	Decimal place
<b>Hematology</b>		
Red blood cell (RBC)	$\times 10^6 / \mu\text{L}$	2
Hemoglobin	g/dL	1
Hematocrit	%	1
Mean corpuscular volume (MCV)	fL	1
Mean corpuscular hemoglobin (MCH)	pg	1
Mean corpuscular hemoglobin concentration (MCHC)	g/dL	1
Platelet	$\times 10^3 / \mu\text{L}$	0
White blood cell (WBC)	$\times 10^3 / \mu\text{L}$	2
Differential WBC	%	0
<b>Biochemistry</b>		
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
$\gamma$ -Glutamyl transpeptidase ( $\gamma$ -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