

グリシドールのラットを用いた  
吸入によるがん原性試験報告書

試験番号：0342

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

STUDY NO. : 0342  
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													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MORIBUND SACRIFICE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : MALE

PAGE : 2

Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MORIBUND SACRIFICE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0



STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
 ALL ANIMALS

SEX : MALE

PAGE : 3

Clinical sign	Group Name	Administration Week-day													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MORIBUND SACRIFICE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
 ALL ANIMALS

SEX : MALE

PAGE : 4

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MORIBUND SACRIFICE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
 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													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	0 ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	1
	3 ppm	0	1	1	1	1	1	1	1	1	1	1	1	1	2
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
MORIBUND SACRIFICE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
LOCOMOTOR MOVEMENT DECR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
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CLINICAL OBSERVATION (SUMMARY)  
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Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	0 ppm	1	1	1	1	1	1	1	1	2	2	2	2	2	2
	3 ppm	2	2	2	2	2	2	2	3	3	3	3	3	3	3
	10 ppm	0	0	0	0	0	0	0	0	0	2	2	2	2	3
	30 ppm	1	2	2	2	3	3	3	3	3	4	4	4	4	4
MORIBUND SACRIFICE	0 ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	1
	3 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	1	1	1	1	1	1	1	1	1	2	2	3	3	4
LOCOMOTOR MOVEMENT DECR	0 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	1	0	1	0	0
LATERAL	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	1
PARALYTIC GAIT	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	0 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	1	1	0	0	0	0
SOILED	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
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CLINICAL OBSERVATION (SUMMARY)  
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Clinical sign	Group Name	Administration Week-day													
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	0 ppm	2	2	2	2	2	2	2	3	3	3	4	4	4	4
	3 ppm	3	3	3	4	5	5	5	6	6	6	6	6	6	6
	10 ppm	3	3	3	3	3	3	3	3	3	3	4	4	4	4
	30 ppm	4	4	4	4	4	4	4	4	4	5	5	5	7	8
MORIBUND SACRIFICE	0 ppm	1	2	2	2	2	2	2	2	3	3	3	4	4	4
	3 ppm	1	1	1	1	1	1	1	1	1	1	1	2	2	2
	10 ppm	0	1	1	1	1	1	2	3	3	3	3	3	4	4
	30 ppm	4	4	4	5	7	7	8	8	8	9	9	9	9	11
LOCOMOTOR MOVEMENT DECR	0 ppm	0	0	0	0	0	0	0	0	1	0	0	1	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	10 ppm	0	1	0	0	0	0	0	0	0	0	0	0	1	0
	30 ppm	0	0	0	0	1	0	0	0	0	1	0	0	0	2
LATERAL	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	2	1	1	0	2
PARALYTIC GAIT	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	30 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	2
SOILED	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	30 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					
		99-7	100-7	101-7	102-7	103-7	104-7
		1	1	1	1	1	1
DEATH	0 ppm	4	4	5	6	6	6
	3 ppm	6	6	6	6	6	6
	10 ppm	5	5	5	5	6	6
	30 ppm	9	9	10	10	11	12
MORIBUND SACRIFICE	0 ppm	4	4	4	4	4	4
	3 ppm	2	2	2	2	2	2
	10 ppm	4	4	5	6	6	6
	30 ppm	13	13	14	15	15	15
LOCOMOTOR MOVEMENT DECR	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	1	0	0	0
	30 ppm	0	0	1	1	0	0
LATERAL	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
HUNCHBACK POSITION	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	2	2	2	3	2	5
PARALYTIC GAIT	0 ppm	0	0	1	0	0	1
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
WASTING	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	1	0	0
SOILED	0 ppm	0	0	1	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	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													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
PILOERECTION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	1	1	1	1	1	1
	30 ppm	0	0	0	0	0	0	0	0	1	1	1	1	1	1
EYE OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL GROWTH OF TEETH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
PILORECTION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	30 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
EYE OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	0 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	30 ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	1
CORNEAL OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL GROWTH OF TEETH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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				32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		29-7	30-7	31-7												
		1	1	1		1	1	1	1	1	1	1	1	1	1	1
PILOERECTION	0 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	0 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	0 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	0 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	1		1	1	1	1	1	1	1	1	1	1	1
	30 ppm	1	1	1		1	1	1	1	1	1	1	1	1	1	1
EYE OPACITY	0 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
CATARACT	0 ppm	1	1	1		1	1	1	1	1	1	1	1	1	1	1
	3 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	1		1	1	1	1	1	1	1	1	1	1	1
	30 ppm	1	1	1		1	1	1	1	1	1	1	1	1	1	1
CORNEAL OPACITY	0 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
ABNORMAL GROWTH OF TEETH	0 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	30 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													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
PILOERECTION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	30 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
EYE OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	0 ppm	1	1	1	1	1	1	1	1	2	2	2	2	2	2
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	30 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
CORNEAL OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL GROWTH OF TEETH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
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													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
PILOERECTION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0
EXOPHTHALMOS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	30 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
EYE OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	0 ppm	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	30 ppm	1	1	1	1	1	1	2	2	2	2	2	2	2	2
CORNEAL OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL GROWTH OF TEETH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
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				74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		71-7	72-7	73-7												
		1	1	1		1	1	1	1	1	1	1	1	1	1	1
PILOERECTION	0 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0		0	0	0	0	0	0	1	0	0	0	0
FROG BELLY	0 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	1
	30 ppm	0	1	1		1	0	0	1	1	2	2	2	2	1	1
SOILED PERI GENITALIA	0 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0		0	0	0	0	0	0	1	0	0	0	0
EXOPHTHALMOS	0 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	1		0	0	0	0	0	0	0	0	0	0	0
	30 ppm	1	1	1		0	0	0	0	0	0	0	0	0	0	0
EYE OPACITY	0 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
CATARACT	0 ppm	3	3	3		3	3	3	3	3	3	3	3	3	3	3
	3 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	1		1	1	1	1	1	1	1	1	1	1	1
	30 ppm	2	2	2		2	2	2	2	2	2	2	2	2	3	3
CORNEAL OPACITY	0 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
ABNORMAL GROWTH OF TEETH	0 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
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													
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
PILOERECTON	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
FROG BELLY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	1	1	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	1	1	1	2	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	0 ppm	1	0	0	0	0	0	0	0	1	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	1	1	1	2	1	1	1	1	1	1
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	1	1	1	1	1	0	0	0	0	0	0
EYE OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	1	1	1	1	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	0 ppm	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	30 ppm	3	3	3	3	3	2	2	2	1	1	1	1	1	1
CORNEAL OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
ABNORMAL GROWTH OF TEETH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
 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					
		99-7	100-7	101-7	102-7	103-7	104-7
		1	1	1	1	1	1
PILOERECTION	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	1	0	1
FROG BELLY	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	1	1	0	0	0
SOILED PERI GENITALIA	0 ppm	0	0	1	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
EXOPHTHALMOS	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
EYE OPACITY	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	1
CATARACT	0 ppm	3	3	3	3	3	3
	3 ppm	0	0	0	0	0	0
	10 ppm	1	1	1	1	1	1
	30 ppm	0	0	0	0	0	0
CORNEAL OPACITY	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
ABNORMAL GROWTH OF TEETH	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0

STUDY NO. : 0342  
 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													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
INTERNAL MASS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. NOSE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EYE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ORAL CAVITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. MANDIBULAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
ANIMAL : RAT F944/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : MALE

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Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
INTERNAL MASS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. NOSE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EYE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ORAL CAVITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. MANDIBULAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0



STUDY NO. : 0342  
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													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
INTERNAL MASS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. NOSE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EYE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ORAL CAVITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. MANDIBULAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EAR	0 ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
INTERNAL MASS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. NOSE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EYE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ORAL CAVITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. MANDIBULAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EAR	0 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	30 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													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
INTERNAL MASS	0 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. NOSE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EYE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	1	1	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ORAL CAVITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	2	2	2
M. MANDIBULAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	1	1	1	1	1	1	1	1	1
M. EAR	0 ppm	1	1	1	1	1	1	2	2	2	2	2	2	2	2
	3 ppm	0	0	1	1	1	1	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
	10 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	30 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													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
INTERNAL MASS	0 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. NOSE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	1	1	1	1	1	1	1	1	1	1	1	1
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EYE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
M. ORAL CAVITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	2	1	1	1	1	1	1	1	1	1	0	0	0	0
M. MANDIBULAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. EAR	0 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	1	1	1	1	1	1	1	0	0	0	0	0	0	0
	10 ppm	1	1	1	1	1	1	1	1	1	0	0	0	0	0
	30 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1

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Clinical sign	Group Name	Administration Week-day													
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
INTERNAL MASS	0 ppm	1	0	0	0	0	0	0	0	0	0	1	2	1	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	2
M. NOSE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	1	1	0	1	2	2	1	1	1	2
M. EYE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	1	1	1	1	0	0
M. PERI MOUTH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	1	2	2	2	2
	30 ppm	1	1	1	1	1	1	1	1	0	0	0	0	1	1
M. ORAL CAVITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. MANDIBULAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EAR	0 ppm	2	1	1	1	1	1	1	1	1	1	1	1	1	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	1	1	1	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	30 ppm	1	1	1	0	0	0	0	0	1	1	1	1	1	1

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Clinical sign	Group Name	Administration Week-day					
		99-7	100-7	101-7	102-7	103-7	104-7
		1	1	1	1	1	1
INTERNAL MASS	0 ppm	1	1	1	0	0	1
	3 ppm	0	0	0	0	0	0
	10 ppm	1	1	1	1	1	1
	30 ppm	1	1	1	1	1	1
M. NOSE	0 ppm	0	0	0	0	0	0
	3 ppm	1	1	1	1	1	1
	10 ppm	1	1	1	1	1	1
	30 ppm	1	1	1	2	1	3
M. EYE	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	1	1
M. PERI MOUTH	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	2	2	2	2	2	2
	30 ppm	2	2	2	2	2	2
M. ORAL CAVITY	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
M. MANDIBULAR	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
M. EAR	0 ppm	1	1	1	1	1	1
	3 ppm	0	0	0	0	1	0
	10 ppm	0	1	1	1	0	0
	30 ppm	0	0	0	0	0	0
M. PERI EAR	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	1	1	1	1	1	1

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Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NECK	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ANTERIOR. DORSUM	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. POSTERIOR DORSUM	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HINDLIMB	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NECK	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ANTERIOR. DORSUM	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. POSTERIOR DORSUM	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HINDLIME	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0



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		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NECK	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ANTERIOR DORSUM	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. POSTERIOR DORSUM	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HINDLIMB	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NECK	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	0 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	1	2	2	2	2	2	2	2	2	2
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ANTERIOR. DORSUM	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. POSTERIOR DORSUM	0 ppm	0	0	0	1	1	1	1	1	1	1	1	1	1	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HINDLIMB	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NECK	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	0 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	1	1	2	2	2	2
M. ABDOMEN	0 ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	30 ppm	0	1	1	1	1	1	1	1	1	1	1	1	1	1
M. ANTERIOR. DORSUM	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. POSTERIOR DORSUM	0 ppm	1	1	1	1	2	1	1	1	1	1	1	1	1	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	1
	10 ppm	0	0	0	1	1	1	1	1	1	1	1	1	1	1
	30 ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	1
M. HINDLIMB	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	0 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NECK	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	1	1	1	1	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	0 ppm	1	1	1	1	1	1	1	1	0	0	0	0	2	2
	3 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	10 ppm	0	1	1	1	1	1	1	1	1	0	0	0	0	0
	30 ppm	2	2	3	3	3	3	3	3	3	3	3	3	3	3
M. ABDOMEN	0 ppm	1	1	2	2	2	1	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	2	2	2	2	2	2	2	2	2	1	1	1	1	1
	30 ppm	1	1	1	1	0	0	0	0	0	0	0	0	0	0
M. ANTERIOR. DORSUM	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	1	1	1	0	1	1	2	2
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
M. POSTERIOR DORSUM	0 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	3 ppm	1	1	1	1	1	1	1	2	2	2	2	2	2	2
	10 ppm	1	1	1	2	2	2	2	2	2	2	2	2	2	2
	30 ppm	0	1	1	1	1	1	1	1	1	1	1	1	1	1
M. HINDLIMB	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
M. GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	0 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	30 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													
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NECK	0 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	0 ppm	2	2	2	2	3	3	3	3	3	3	4	4	5	5
	3 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	10 ppm	0	0	0	1	1	1	1	1	1	1	1	1	1	1
	30 ppm	3	3	3	3	3	3	3	3	3	4	4	4	3	2
M. ABDOMEN	0 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	10 ppm	1	1	1	1	2	2	1	1	1	1	1	1	1	1
	30 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	2
M. ANTERIOR. DORSUM	0 ppm	0	1	1	1	1	1	1	0	0	0	0	0	0	0
	3 ppm	0	0	0	1	2	2	1	1	1	1	1	1	1	1
	10 ppm	2	2	2	3	4	4	4	4	4	4	4	4	4	4
	30 ppm	1	1	1	1	1	1	0	0	0	0	1	1	1	1
M. POSTERIOR DORSUM	0 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	3 ppm	2	2	2	2	2	2	2	2	2	2	2	2	3	3
	10 ppm	2	2	1	1	1	1	1	1	1	1	1	1	1	1
	30 ppm	1	1	1	1	2	2	2	2	2	2	2	2	2	2
M. HINDLIMB	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	1	1	1	1	2	1	1	1	1	1	1	1	1	1
M. GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	0 ppm	1	0	1	1	1	0	0	0	1	1	0	3	2	2
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	0	1	1	1	0	0	0	0	0	0	0	0
	30 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					
		99-7	100-7	101-7	102-7	103-7	104-7
		1	1	1	1	1	1
M. NECK	0 ppm	1	1	1	1	1	1
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	1	0	0	0
	30 ppm	0	0	0	0	0	0
M. BREAST	0 ppm	6	6	5	5	5	5
	3 ppm	1	1	1	1	1	1
	10 ppm	0	0	0	0	1	1
	30 ppm	1	1	1	1	0	1
M. ABDOMEN	0 ppm	1	2	2	3	3	3
	3 ppm	1	1	1	2	2	2
	10 ppm	1	1	1	2	2	2
	30 ppm	2	2	2	3	3	3
M. ANTERIOR. DORSUM	0 ppm	0	0	0	0	0	0
	3 ppm	1	1	1	1	1	1
	10 ppm	4	4	4	3	3	3
	30 ppm	1	3	3	5	5	5
M. POSTERIOR DORSUM	0 ppm	1	1	1	1	1	1
	3 ppm	3	3	3	3	3	3
	10 ppm	1	1	1	1	1	1
	30 ppm	2	2	2	2	2	2
M. HINDLIMB	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	1	1	1	1	1	1
M. GENITALIA	0 ppm	0	0	0	0	0	0
	3 ppm	1	1	1	1	1	1
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
ANEMIA	0 ppm	2	1	0	0	0	0
	3 ppm	0	0	0	0	0	1
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0

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Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
CRUSTA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BRADYPNEA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SHALLOW BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
CRUSTA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BRADYPNEA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SHALLOW BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
CRUSTA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BRADYPNEA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SHALLOW BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
CRUSTA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BRADYPNEA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SHALLOW BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
CRUSTA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BRADYPNEA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SHALLOW BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
CRUSTA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	0
	30 ppm	0	0	0	0	0	0	0	0	1	1	0	1	0	1
BRADYPNEA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SHALLOW BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	1	1	1	0	0	0	0
SUBNORMAL TEMP	0 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0

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Clinical sign	Group Name	Administration Week-day													
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
CRUSTA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	1	0	0	0	1	1	0
	30 ppm	0	0	0	0	2	1	0	0	1	1	0	0	0	4
BRADYPNEA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	1
SHALLOW BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	1	1	0	0	2	2	2	2	1	2
SUBNORMAL TEMP	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	1	0	0	0	0	0	0	0	0	0	0	1	0
	30 ppm	0	0	0	0	2	0	0	0	0	0	0	0	0	2

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Clinical sign	Group Name	Administration Week-day					
		99-7	100-7	101-7	102-7	103-7	104-7
		1	1	1	1	1	1
CRUSTA	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	1	1	1
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
TORTICOLLIS	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	1	0	0	0
	30 ppm	0	0	0	0	0	0
IRREGULAR BREATHING	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	1	0	0	0
	30 ppm	2	3	4	7	6	8
BRADYPNEA	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	1	0	1
SHALLOW BREATHING	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	1	4	4	7	6	9
SUBNORMAL TEMP	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	1	0	0	0

(HAN190)

BAIS 3

## APPENDIX A 2

CLINICAL OBSERVATION : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0342  
 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													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MORIBUND SACRIFICE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0



STUDY NO. : 0342  
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													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MORIBUND SACRIFICE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
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													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MORIBUND SACRIFICE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
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													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MORIBUND SACRIFICE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
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													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	0 ppm	0	0	0	0	0	1	1	1	1	1	1	1	1	2
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	1	1	1	1	1	1	1	1	1	1	1
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MORIBUND SACRIFICE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	0 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
 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													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	0 ppm	2	2	2	3	3	3	3	3	3	3	3	4	4	4
	3 ppm	0	0	0	1	1	1	1	1	2	2	2	2	2	2
	10 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	30 ppm	0	0	1	1	1	1	1	1	2	2	2	3	3	3
MORIBUND SACRIFICE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	30 ppm	0	0	0	0	0	0	2	2	2	2	2	2	2	2
LOCOMOTOR MOVEMENT DECR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LATERAL	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	1	1	0	0	0
PARALYTIC GAIT	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
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													
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	0 ppm	4	4	4	4	4	4	4	4	4	4	5	5	6	7
	3 ppm	2	2	2	2	4	6	6	6	6	7	7	8	10	10
	10 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	2
	30 ppm	3	3	3	4	4	4	4	4	4	4	5	5	5	6
MORIBUND SACRIFICE	0 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	3 ppm	0	0	0	0	0	1	1	1	1	2	2	2	2	2
	10 ppm	1	1	1	3	3	3	3	3	3	3	3	4	4	4
	30 ppm	2	2	3	3	3	3	3	4	6	6	6	8	8	10
LOCOMOTOR MOVEMENT DECR	0 ppm	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	1	0	0	0	1	0	0	0	0
	10 ppm	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	1	1	0	0	2	0	1
LATERAL	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	1	0	0	0	0	0
HUNCHBACK POSITION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0	1
SOILED	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	1	1	0	0	0	0	0	0

STUDY NO. : 0342  
 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					
		99-7	100-7	101-7	102-7	103-7	104-7
		1	1	1	1	1	1
DEATH	0 ppm	7	7	7	7	7	7
	3 ppm	10	10	10	10	10	10
	10 ppm	2	3	3	3	3	3
	30 ppm	6	6	6	6	6	6
MORIBUND SACRIFICE	0 ppm	2	2	2	2	2	2
	3 ppm	2	2	2	2	2	2
	10 ppm	5	6	6	7	7	7
	30 ppm	10	11	11	11	12	12
LOCOMOTOR MOVEMENT DECR	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	1	1	0	1	0	0
	30 ppm	0	1	0	0	1	0
LATERAL	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
HUNCHBACK POSITION	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
PARALYTIC GAIT	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
WASTING	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	1	0	0
	30 ppm	0	0	0	0	0	0
SOILED	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	1	0	0
	30 ppm	0	0	0	0	0	0

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
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CLINICAL OBSERVATION (SUMMARY)  
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Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
PILOERECTION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	0 ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	0 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTERIOS CHAMBER OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
PILORECTION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	0 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	0 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	3 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	10 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTERIOS CHAMBER OPACITY	0 ppm	0	0	1	1	1	1	1	1	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
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Clinical sign	Group Name	Administration Week-day													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
PILORECTION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	0 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	0 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	3 ppm	1	1	1	2	2	2	2	2	2	2	2	2	2	2
	10 ppm	1	1	2	2	2	2	2	2	2	2	2	2	2	2
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTERIOS CHAMBER OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
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Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
PILOERECTION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	0 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	0 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	3 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	10 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTERIOR CHAMBER OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
PILOERECTION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	1	0	1	1	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	0 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	0 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	3 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	10 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTERIOR CHAMBER OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
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													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
PILOERECTION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	1	1	1	1	1	1
FROG BELLY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	30 ppm	0	1	0	0	0	0	0	0	0	0	1	0	0	0
SOILED PERI GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	0 ppm	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	1	1	1	1	1	1	1	1	1	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	0 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	3 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	10 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTERIOR CHAMBER OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	0 ppm	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	30 ppm	0	0	0	0	0	0	0	0	1	1	1	0	0	0

STUDY NO. : 0342  
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													
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
PILOERECTION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	1	1	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	1	1	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
SOILED PERI GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	1	1	1	0	0	0	0	0	0	0	0	1	0
	30 ppm	0	0	1	0	0	0	1	1	1	1	0	1	0	1
EXOPHTHALMOS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	0 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	2
	3 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	10 ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTERIOS CHAMBER OPACITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	0 ppm	1	1	1	2	1	1	1	1	1	1	0	0	0	0
	3 ppm	0	0	1	1	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	1	1	0	0	0	0	0	1	1	0	1	2
	30 ppm	0	0	1	0	0	0	0	0	0	1	0	0	0	0

STUDY NO. : 0342  
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					
		99-7	100-7	101-7	102-7	103-7	104-7
		1	1	1	1	1	1
PILOERECTION	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
FROG BELLY	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
SOILED PERI GENITALIA	0 ppm	1	1	1	1	1	1
	3 ppm	0	0	0	0	0	1
	10 ppm	1	0	0	0	0	0
	30 ppm	0	0	0	0	1	0
EXOPHTHALMOS	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
CATARACT	0 ppm	2	3	3	3	3	3
	3 ppm	2	2	2	2	2	2
	10 ppm	2	2	2	2	2	2
	30 ppm	0	0	0	0	0	0
CORNEAL OPACITY	0 ppm	0	0	0	0	0	1
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
ANTERIOR CHAMBER OPACITY	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
INTERNAL MASS	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	1	1	2
	10 ppm	2	3	2	2	1	2
	30 ppm	0	0	1	2	2	3

STUDY NO. : 0342  
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CLINICAL OBSERVATION (SUMMARY)  
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Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NOSE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EYE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ORAL CAVITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. MANDIBULAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HEAD	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0



STUDY NO. : 0342  
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													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NOSE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EYE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ORAL CAVITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. MANDIBULAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HEAD	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
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													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NOSE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EYE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ORAL CAVITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. MANDIBULAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HEAD	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
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SEX : FEMALE

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Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NOSE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EYE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ORAL CAVITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. MANDIBULAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	1	1	1	1	1	1	1	1	1	1	1
M. PERI EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HEAD	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
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Clinical sign	Group Name	Administration Week-day													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NOSE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EYE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ORAL CAVITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. MANDIBULAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. PERI EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	1	1	1	1	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HEAD	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NOSE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EYE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ORAL CAVITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. MANDIBULAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. PERI EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HEAD	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NOSE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EYE	0 ppm	1	1	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI MOUTH	0 ppm	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ORAL CAVITY	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. MANDIBULAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
M. EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	0
M. PERI EAR	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HEAD	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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					
		99-7	100-7	101-7	102-7	103-7	104-7
		1	1	1	1	1	1
M. NOSE	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	1	1	1	1	1	1
	30 ppm	0	0	0	0	0	0
M. EYE	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
M. PERI MOUTH	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
M. ORAL CAVITY	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	1	1	1	1
M. MANDIBULAR	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	1	1	1	1	1	1
M. EAR	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
M. PERI EAR	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
M. HEAD	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0

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Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NECK	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. POSTERIOR DORSUM	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CRUSTA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NECK	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. POSTERIOR DORSUM	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CRUSTA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NECK	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. POSTERIOR DORSUM	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CRUSTA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NECK	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. POSTERIOR DORSUM	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CRUSTA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NECK	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. POSTERIOR DORSUM	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	1	1	1	1	1	1
M. GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CRUSTA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NECK	0 ppm	0	0	0	0	0	0	1	1	1	1	1	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	0 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	10 ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	2
	30 ppm	1	1	1	1	1	1	1	1	1	1	1	2	2	2
M. ABDOMEN	0 ppm	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	1	1	1	1	1	1	1	1	1	1	1	1
M. POSTERIOR DORSUM	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDISE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CRUSTA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	1	1	1	1	1	1	1	1	1	1	1

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Clinical sign	Group Name	Administration Week-day													
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. NECK	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	0 ppm	1	1	1	1	1	1	2	2	2	3	3	3	3	3
	3 ppm	1	0	0	0	0	0	1	1	1	1	1	1	0	0
	10 ppm	2	3	3	2	1	1	1	2	2	2	3	4	4	5
	30 ppm	2	3	3	4	4	4	5	5	5	4	4	4	5	8
M. ABDOMEN	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	3 ppm	0	0	0	1	1	1	1	1	1	1	2	2	1	1
	10 ppm	0	0	0	0	0	1	1	1	1	2	2	2	2	1
	30 ppm	1	1	1	1	1	1	1	1	2	2	2	2	4	3
M. POSTERIOR DORSUM	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. GENITALIA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	1	1	1	0	0	0	0	0
	10 ppm	0	0	1	1	1	1	1	1	1	1	1	1	1	2
	30 ppm	0	0	0	0	0	0	1	1	0	0	1	1	1	0
ANEMIA	0 ppm	0	0	0	0	1	0	0	0	0	1	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	1	1	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	0
JAUNDISE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
CRUSTA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1

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Clinical sign	Group Name	Administration Week-day					
		99-7	100-7	101-7	102-7	103-7	104-7
		1	1	1	1	1	1
M. NECK	0 ppm	0	0	0	0	0	1
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
M. BREAST	0 ppm	4	4	4	4	4	4
	3 ppm	1	1	1	3	3	3
	10 ppm	5	5	6	7	7	8
	30 ppm	8	8	7	9	9	12
M. ABDOMEN	0 ppm	1	2	2	2	2	3
	3 ppm	1	2	2	2	2	2
	10 ppm	1	2	3	5	5	5
	30 ppm	3	3	3	3	3	6
M. POSTERIOR DORSUM	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	1	1	1	1	1	1
M. GENITALIA	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	2	1	1	1	1	1
	30 ppm	0	0	0	0	0	0
ANEMIA	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	1	0	0	0	0
	30 ppm	0	1	0	0	1	1
JAUNDISE	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
CRUSTA	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	1	1	1	1	1	1

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Clinical sign	Group Name	Administration Week-day													
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
HEMORRHAGE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BRADYPNEA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SALIVATION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 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													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
HEMORRHAGE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BRADYPNEA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SALIVATION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
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													
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
HEMORRHAGE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BRADYPNEA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SALIVATION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
 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													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
HEMORRHAGE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BRADYPNEA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SALIVATION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
 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													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
HEMORRHAGE	0 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BRADYPNEA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SALIVATION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
 ALL ANIMALS

SEX : FEMALE

PAGE : 78

Clinical sign	Group Name	Administration Week-day													
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
HEMORRHAGE	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	2	2	2	0	0	0	0	0	0	0	0
BRADYPNEA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SALIVATION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

PAGE : 79

Clinical sign	Group Name	Administration Week-day													
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
HEMORRHAGE	0 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0
IRREGULAR BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	1	0	0	0	1	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	1	1	0	0	2	0	0
BRADYPNEA	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	1	1	0	0	0	0	0
DEEP BREATHING	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
SUBNORMAL TEMP	0 ppm	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	10 ppm	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0	0	0	1	0	0	1	0	1
SALIVATION	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	30 ppm	1	1	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
 ALL ANIMALS

SEX : FEMALE

PAGE : 80

Clinical sign	Group Name	Administration Week-day					
		99-7	100-7	101-7	102-7	103-7	104-7
		1	1	1	1	1	1
HEMORRHAGE	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
IRREGULAR BREATHING	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	1	1	0	0	0	0
	30 ppm	0	1	0	0	1	0
BRADYPNEA	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	1	0	0	0	0
	30 ppm	0	0	0	0	0	0
DEEP BREATHING	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0
SUBNORMAL TEMP	0 ppm	0	0	0	0	0	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	1	0	1	0	0
	30 ppm	0	0	0	0	0	0
SALIVATION	0 ppm	0	0	0	1	1	0
	3 ppm	0	0	0	0	0	0
	10 ppm	0	0	0	0	0	0
	30 ppm	0	0	0	0	0	0

## APPENDIX B 1

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



STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrJ  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 1

Group Name	Administration week		1		2		3		4		5		6	
	0													
0 ppm	122±	4	152±	6	180±	8	204±	10	221±	11	242±	12	256±	13
3 ppm	122±	4	152±	6	180±	8	202±	10	219±	11	238±	12	252±	14
10 ppm	122±	4	152±	6	180±	7	203±	9	219±	10	238±	11	251±	12
30 ppm	122±	4	152±	6	179±	7	201±	8	217±	9	235±	10	249±	12*

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 2

Group Name	Administration week											
	7		8		9		10		11		12	
0 ppm	270±	14	280±	15	289±	15	297±	16	304±	17	311±	16
3 ppm	265±	14	276±	15	284±	16	292±	17	299±	17	305±	17
10 ppm	264±	13*	274±	14	283±	15	291±	15	298±	16	305±	17
30 ppm	261±	13**	271±	13**	279±	13**	288±	14*	295±	15*	300±	16**

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 3

Group Name	Administration week											
	14	18	22	26	30	34	38					
0 ppm	324± 17	340± 19	354± 20	368± 20	378± 22	387± 23	393± 23					
3 ppm	319± 19	337± 20	350± 22	365± 24	376± 25	385± 26	393± 26					
10 ppm	317± 17	333± 18	347± 18	359± 19	368± 21	378± 21	384± 21					
30 ppm	313± 16**	328± 17**	341± 18**	351± 19**	360± 19**	370± 20**	377± 20**					

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 4

Group Name	Administration week													
	42		46		50		54		58		62		66	
0 ppm	401±	24	406±	24	412±	24	416±	24	420±	25	422±	25	423±	27
3 ppm	400±	27	405±	27	411±	28	415±	28	417±	30	420±	29	419±	30
10 ppm	391±	22	395±	22	402±	22	407±	22	409±	23	411±	23	411±	25
30 ppm	385±	22**	390±	21**	397±	22**	401±	22**	404±	22**	402±	21**	401±	20**
Significant difference ; * : P ≤ 0.05      ** : P ≤ 0.01      Test of Dunnett														

(HAN260)

BAIS 3

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 5

Group Name	Administration week											
	70		74		78		82		86		90	94
0 ppm	427±	28	427±	32	426±	26	422±	23	421±	23	419±	24
3 ppm	421±	31	419±	34	423±	29	421±	29	423±	30	419±	35
10 ppm	414±	26	415±	30	413±	37	408±	26*	408±	26	406±	26
30 ppm	400±	19**	395±	22**	389±	28**	393±	34**	386±	31**	376±	39**

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 6

Group Name	Administration week					
	98		102		104	
0 ppm	412±	29	406±	42	401±	47
3 ppm	415±	35	413±	44	411±	50
10 ppm	395±	32	395±	37	392±	43
30 ppm	349±	57**	347±	54**	336±	33**

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. : 0342  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 7

Group Name	Administration week		0		1		2		3		4		5		6	
0 ppm	96±	3	110±	5	122±	5	133±	6	139±	7	150±	7	156±	8		
3 ppm	96±	3	109±	4	122±	4	132±	5	138±	5	148±	7	154±	7		
10 ppm	96±	3	110±	5	122±	5	132±	6	138±	6	148±	8	153±	9		
30 ppm	96±	3	110±	4	121±	5	132±	5	137±	5	147±	6	152±	7*		

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

Test of Dunnett

(HAN260)

BAIS 3



STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
UNIT : g  
REPORT TYPE : A1 104  
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 8

Group Name	Administration week													
	7		8		9		10		11		12		13	
0 ppm	162±	9	165±	9	170±	9	176±	9	180±	10	182±	10	185±	11
3 ppm	159±	7	161±	7	166±	8	172±	8	175±	9	178±	9	182±	10
10 ppm	158±	9*	161±	10	166±	10*	171±	10**	174±	11*	176±	11*	180±	11
30 ppm	157±	7**	159±	8**	164±	8**	168±	8**	171±	8**	173±	8**	177±	8**

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 9

Group Name	Administration week		14		18		22		26		30		34		38	
0 ppm	188±	11	192±	11	197±	11	205±	13	211±	12	216±	15	217±	14		
3 ppm	182±	9*	188±	11	195±	11	204±	12	209±	12	215±	13	216±	13		
10 ppm	182±	11*	185±	12**	190±	12**	198±	13*	203±	14**	208±	16**	211±	16		
30 ppm	179±	9**	183±	9**	188±	9**	195±	9**	200±	10**	206±	10**	206±	10**		

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 10

Group Name	Administration		week											
	42		46		50		54		58		62		66	
0 ppm	221±	15	224±	16	227±	16	232±	18	234±	19	240±	20	243±	22
3 ppm	220±	14	225±	16	230±	17	234±	19	235±	18	239±	20	244±	21
10 ppm	214±	16*	219±	15	222±	17	228±	18	230±	19	233±	20	238±	21
30 ppm	211±	11**	215±	11**	220±	12*	225±	13	226±	13*	229±	14*	235±	15

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 11

Group Name	Administration week													
	70		74		78		82		86		90		94	
0 ppm	246±	23	250±	23	254±	23	258±	24	262±	25	266±	25	266±	26
3 ppm	250±	21	254±	20	259±	20	262±	22	266±	21	267±	24	270±	24
10 ppm	244±	22	247±	21	252±	22	256±	22	262±	22	267±	22	267±	22
30 ppm	239±	16	240±	18*	243±	21*	249±	21	252±	25	256±	24	256±	30
Significant difference ;    * : $P \leq 0.05$ ** : $P \leq 0.01$														

(HAN260)

BAIS 3

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 12

Group Name	Administration week					
	98		102		104	
0 ppm	269±	25	270±	27	267±	27
3 ppm	274±	19	272±	21	271±	22
10 ppm	266±	22	267±	29	271±	26
30 ppm	254±	20**	255±	20*	251±	24*
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. : 0342  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 1

Group Name	Administration week						
	1	2	3	4	5	6	7
0 ppm	15.2± 0.9	15.8± 1.1	16.9± 1.1	17.5± 1.2	17.3± 1.3	17.1± 1.2	17.6± 1.3
3 ppm	15.4± 1.0	16.1± 1.2	17.0± 1.3	17.1± 1.2	16.8± 1.1	16.5± 1.3	16.9± 1.0*
10 ppm	15.3± 1.0	16.0± 1.1	16.9± 1.1	17.1± 1.1	16.8± 1.1	16.3± 1.1**	17.0± 1.2*
30 ppm	15.1± 1.0	16.1± 1.1	17.5± 1.3*	17.2± 1.6	17.1± 1.9	16.9± 1.4	17.1± 1.5

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 2

Group Name	Administration week						
	8	9	10	11	12	13	14
0 ppm	17.4± 1.3	17.1± 1.1	16.8± 1.0	16.8± 1.1	16.4± 0.9	16.6± 0.9	16.7± 0.8
3 ppm	16.8± 0.9	16.6± 1.0	16.4± 1.0	16.2± 1.1*	15.7± 1.1**	16.2± 1.2	16.0± 1.2**
10 ppm	16.8± 1.1	16.6± 1.2	16.1± 1.0**	16.0± 1.2**	16.1± 1.2	16.2± 1.1	16.0± 1.1**
30 ppm	17.1± 1.4	16.6± 1.1	16.1± 1.0**	16.5± 1.4	16.2± 1.3	16.2± 1.2	15.9± 1.0**
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett							

(HAN260)

BAIS 3



STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 3

Group Name	Administration week						
	18	22	26	30	34	38	42
0 ppm	16.4± 1.1	16.4± 0.9	16.8± 1.0	16.4± 1.0	16.9± 1.0	17.2± 1.1	17.4± 1.1
3 ppm	16.4± 1.0	16.2± 1.1	16.6± 1.2	16.3± 1.1	16.7± 1.0	17.2± 1.1	17.3± 1.1
10 ppm	16.2± 1.0	16.2± 0.9	16.7± 1.1	16.2± 1.1	16.7± 1.0	16.9± 1.0	17.0± 1.1
30 ppm	15.9± 1.1	16.1± 1.1	16.4± 1.1	16.3± 1.0	16.5± 0.9	16.7± 1.0	17.1± 1.0
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett							

(HAN260)

BAIS 3

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 4

Group Name	Administration week						
	46	50	54	58	62	66	70
0 ppm	17.1± 1.1	17.4± 1.1	17.4± 1.0	17.5± 1.0	17.8± 1.1	17.8± 1.9	17.9± 1.2
3 ppm	17.0± 0.9	17.2± 1.0	17.4± 1.0	17.3± 1.0	17.6± 1.0	17.7± 1.0	17.8± 1.2
10 ppm	16.7± 0.9	16.9± 1.0*	17.0± 0.9	16.8± 1.0**	17.1± 1.1**	17.3± 0.9**	17.4± 1.2*
30 ppm	16.9± 0.9	16.9± 1.1*	17.1± 1.0	16.7± 1.0**	16.9± 0.9**	17.0± 1.8**	16.8± 1.1**
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett							

(HAN260)

BAIS 3

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 5

Group Name	Administration week						
	74	78	82	86	90	94	98
0 ppm	17.8± 1.2	17.9± 1.6	17.9± 1.1	17.3± 1.1	17.1± 1.3	16.1± 2.5	17.2± 1.3
3 ppm	17.4± 2.0	17.6± 1.1	17.9± 1.2	17.4± 1.6	17.0± 1.3	16.9± 1.9	17.7± 1.6
10 ppm	17.2± 1.5*	17.2± 1.6*	16.7± 1.9**	16.9± 1.0	16.4± 1.9*	16.3± 0.9	16.5± 2.1
30 ppm	16.6± 1.5**	16.7± 1.9**	16.7± 1.5**	15.8± 1.5**	16.2± 1.7*	16.1± 2.2	14.7± 5.4*

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
UNIT : g  
REPORT TYPE : A1 104  
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 6

Group Name	Administration week	
	102	104
0 ppm	17.4± 1.5	17.2± 1.9
3 ppm	18.3± 1.6*	18.1± 1.6*
10 ppm	17.0± 1.7	16.9± 1.2
30 ppm	16.2± 1.7*	16.2± 2.1

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

Test of Dunnett

(HAN260)

BAIS 3

## APPENDIX C 2

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

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 7

Group Name	Administration week						
	1	2	3	4	5	6	7
0 ppm	11.0± 0.8	10.8± 0.6	11.3± 0.9	11.7± 0.8	11.8± 0.9	11.5± 1.0	11.9± 1.0
3 ppm	11.3± 0.7	10.5± 0.7*	11.4± 0.8	11.4± 0.7	11.6± 0.9	11.2± 1.0	11.4± 1.1
10 ppm	11.1± 0.8	10.7± 0.7	11.4± 0.9	11.5± 1.2	11.6± 1.9	11.0± 1.4**	11.3± 1.0*
30 ppm	11.0± 0.7	10.7± 0.7	11.6± 0.8	11.3± 0.7*	11.6± 0.8	11.2± 0.8	11.2± 1.0**

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 8

Group Name	Administration week						
	8	9	10	11	12	13	14
0 ppm	10.9± 0.8	11.8± 1.0	12.1± 1.0	12.2± 1.1	11.5± 1.0	11.6± 1.6	11.7± 1.8
3 ppm	10.8± 0.9	11.4± 1.1	11.8± 0.9	11.5± 0.9*	11.1± 0.9	11.6± 1.1	11.1± 0.9
10 ppm	10.9± 0.9	11.1± 0.9**	11.1± 0.8**	11.2± 1.0**	11.3± 1.3	11.4± 1.1	11.3± 1.2
30 ppm	10.5± 0.7	11.0± 0.8**	10.9± 0.8**	11.1± 0.8**	11.1± 0.9	11.2± 0.8	10.9± 0.9**
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett							

(HAN260)

BAIS 3

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrJ  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 9

Group Name	Administration week						
	18	22	26	30	34	38	42
0 ppm	11.2± 1.0	11.2± 1.0	11.6± 1.3	11.6± 1.1	11.7± 1.3	11.8± 1.0	11.8± 0.9
3 ppm	11.2± 1.1	11.2± 1.0	11.9± 1.9	11.6± 1.2	12.1± 1.4	11.9± 1.2	11.8± 1.0
10 ppm	10.6± 0.9*	10.8± 0.8*	11.5± 0.9	11.0± 1.0*	11.8± 1.3	11.6± 1.1	11.4± 0.8
30 ppm	10.9± 0.9	10.7± 0.9**	11.3± 1.2	11.2± 1.0	11.8± 1.1	11.2± 0.8*	11.5± 1.0
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett							

(HAN260)

BAIS 3



STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 10

Group Name	Administration week						
	46	50	54	58	62	66	70
0 ppm	11.8± 1.1	12.1± 1.0	11.9± 1.0	12.0± 0.9	12.6± 1.1	12.7± 1.1	13.0± 1.1
3 ppm	12.2± 1.1	12.3± 1.6	12.1± 1.3	11.9± 0.9	12.4± 1.0	12.8± 1.1	13.1± 1.0
10 ppm	11.8± 1.1	11.8± 1.1	11.9± 1.1	11.6± 1.3	11.7± 1.0**	12.4± 1.0	12.8± 1.1
30 ppm	11.6± 0.8	12.0± 0.9	11.7± 0.9	11.6± 0.7	11.5± 0.8**	12.4± 1.0	12.3± 1.2**

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrJ  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 11

Group Name	Administration week						
	74	78	82	86	90	94	98
0 ppm	12.8± 1.2	12.8± 1.0	12.9± 1.0	12.9± 1.0	12.7± 1.0	12.2± 1.0	13.0± 1.5
3 ppm	12.5± 0.9	12.8± 1.0	12.9± 1.2	12.4± 1.4	12.1± 1.3*	12.1± 2.0	13.0± 1.3
10 ppm	12.2± 1.0*	12.5± 1.2	12.5± 1.2	12.7± 1.1	12.5± 1.0	12.0± 1.7	12.6± 1.4
30 ppm	11.8± 1.1**	12.0± 1.2**	12.4± 1.0	12.2± 1.0**	12.1± 1.3*	11.7± 1.7*	12.6± 1.9
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett							

(HAN260)

BAIS 3

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrJ  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 12

Group Name	Administration week	
	102	104
0 ppm	13.4± 1.2	12.9± 1.3
3 ppm	13.2± 1.3	12.7± 1.6
10 ppm	12.8± 2.2	13.1± 1.2
30 ppm	12.3± 1.4**	11.9± 2.3
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett		

(HAN260)

BAIS 3

## APPENDIX D 1

HEMATOLOGY : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0342  
 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>9</sup> /μl	
0 ppm	39	8.38±	1.39	13.9±	2.3	42.9±	6.1	51.6±	4.0	16.7±	1.3	32.3±	1.1	868±	209
3 ppm	40	7.93±	1.32	13.0±	2.7	40.6±	7.0	51.3±	3.2	16.2±	1.5	31.6±	1.9	1009±	320
10 ppm	36	8.50±	1.49	13.8±	2.8	43.0±	7.5	50.8±	3.2	16.2±	1.3	32.0±	1.5	892±	181
30 ppm	21	8.61±	1.55	13.9±	3.1	43.5±	8.4	50.4±	2.8	16.0±	1.5	31.8±	1.8	852±	215

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

Test of Dunnett

(HCL070)

BAIS 3

STUDY NO. : 0342  
 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		OTHER	
0 ppm	39	6.19±	2.46	1±	1	42±	11	2±	2	0±	0	5±	3	47±	10	3±	5
3 ppm	40	5.84±	1.77	1±	1	41±	11	2±	2	0±	0	5±	2	47±	10	4±	5
10 ppm	36	5.52±	1.37	1±	1	40±	9	2±	1	0±	0	4±	2	48±	10	4±	5
30 ppm	21	7.47±	2.89	1±	2	45±	14	1±	1*	0±	0	4±	2	42±	14	6±	8

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 3

## APPENDIX D 2

### HEMATOLOGY : SUMMARY, RAT : FEMALE (2-YEAR STUDY)

STUDY NO. : 0342  
 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	
0 ppm	41	8.25±	0.99	15.0±	1.6	44.6±	4.1	54.7±	5.2	18.3±	1.3	33.6±	0.8	605±	84
3 ppm	38	8.27±	0.50	14.9±	1.0	44.7±	2.5	54.1±	1.9	18.1±	0.7	33.4±	0.7	603±	109
10 ppm	39	8.18±	0.66	14.8±	1.2	44.2±	3.0	54.2±	2.3	18.1±	0.7	33.4±	0.6	618±	69
30 ppm	32	7.67±	1.21**	14.0±	2.0**	42.3±	5.0**	55.9±	6.0	18.4±	1.3	33.0±	1.6*	656±	135

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 3



STUDY NO. : 0342

ANIMAL : RAT F344/DuCrj

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

## HEMATOLOGY (SUMMARY)

ALL ANIMALS (105W)

PAGE : 4

Group Name	NO. of Animals	WBC 10 <sup>3</sup> /μl		Differential		WBC (%)		EOSINO		BASO		MONO		LYMPHO		OTHER	
				N-BAND		N-SEG											
0 ppm	41	4.50±	11.04	1±	1	39±	12	2±	1	0±	0	5±	2	48±	11	5±	16
3 ppm	38	3.02±	2.41	1±	1	39±	13	2±	1	0±	0	5±	2	50±	13	3±	5
10 ppm	39	3.54±	3.21	1±	1	37±	11	2±	1	0±	0	5±	2	53±	10	3±	4
30 ppm	32	8.00±	15.25**	1±	2	38±	16	1±	1	0±	0	4±	2	45±	17	10±	23

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

Test of Dunnett

(HCL070)

BAIS 3

APPENDIX E 1

BIOCHEMISTRY : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0342  
 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	
0 ppm	39	6.3±	0.6	3.3±	0.3	1.1±	0.1	0.21±	0.22	146±	29	187±	62	118±	85
3 ppm	41	6.4±	0.5	3.4±	0.3	1.1±	0.1	0.16±	0.06	155±	23	193±	68	133±	77
10 ppm	37	6.4±	0.3	3.4±	0.3	1.1±	0.1	0.18±	0.03	157±	22	189±	73	129±	87
30 ppm	21	6.3±	0.8	3.1±	0.3*	1.0±	0.2**	0.18±	0.08	135±	35	209±	71	167±	177

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 3

STUDY NO. : 0342  
 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	
0 ppm	39	269±	93	114±	125	48±	36	215±	97	208±	98	11±	7	105±	36
3 ppm	41	280±	82	75±	41	34±	14	193±	54	207±	72	11±	6	93±	17
10 ppm	37	274±	104	78±	28	36±	15	195±	46	200±	61	13±	8	91±	12
30 ppm	21	332±	167	110±	81	50±	33	218±	73	232±	128	14±	10	106±	23

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 3

STUDY NO. : 0342  
 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	
0 ppm	39	21.1±	5.1	0.6±	0.1	143±	2	3.9±	0.3	106±	2	10.2±	0.4	4.2±	0.7
3 ppm	41	22.1±	5.8	0.5±	0.1	143±	2	3.9±	0.4	106±	2	10.3±	0.3	4.4±	0.6
10 ppm	37	21.3±	5.0	0.5±	0.1	143±	1	3.8±	0.3	106±	2	10.3±	0.4	4.2±	0.6
30 ppm	21	22.8±	4.4	0.5±	0.1	142±	1	3.9±	0.5	104±	2**	10.3±	0.5	4.5±	0.8

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

Test of Dunnett

(HCL074)

BAIS 3

## APPENDIX E 2

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

STUDY NO. : 0342  
 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	
0 ppm	41	6.8±	0.4	4.0±	0.3	1.5±	0.2	0.16±	0.09	144±	15	140±	27	75±	57
3 ppm	38	6.8±	0.4	3.9±	0.4	1.4±	0.2	0.15±	0.05	143±	18	158±	65	105±	161
10 ppm	39	6.7±	0.3	4.0±	0.3	1.4±	0.2	0.15±	0.03	147±	13	140±	29	74±	32
30 ppm	32	6.6±	0.4	3.8±	0.2	1.4±	0.2	0.16±	0.06	143±	23	149±	67	87±	72

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

Test of Dunnett

(HCL074)

BAIS 3

STUDY NO. : 0342  
 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	
0 ppm	41	253±	41	138±	152	57±	27	264±	206	132±	57	5±	4	96±	36
3 ppm	38	275±	103	139±	66	61±	26	265±	93	136±	66	5±	2	95±	27
10 ppm	39	251±	49	151±	79	63±	31	287±	154	124±	51	5±	3	93±	40
30 ppm	32	262±	96	157±	114	55±	23	307±	245	151±	72	6±	5	100±	50

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 3



STUDY NO. : 0342

ANIMAL : RAT F344/DuCrj

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

## BIOCHEMISTRY (SUMMARY)

ALL ANIMALS (105W)

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	
0 ppm	41	18.8±	2.1	0.5±	0.1	142±	1	3.6±	0.4	104±	2	10.2±	0.3	3.8±	0.7
3 ppm	38	19.3±	2.5	0.5±	0.1	141±	2	3.6±	0.4	104±	2	10.4±	0.5	4.1±	0.7
10 ppm	39	18.2±	1.6	0.5±	0.1	141±	1	3.4±	0.4	104±	2	10.2±	0.3	3.9±	0.7
30 ppm	32	18.0±	2.4	0.5±	0.1	142±	1	3.5±	0.4	104±	2	10.1±	0.4	4.1±	0.5

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

Test of Dunnett

(HCL074)

BAIS 3

## APPENDIX F 1

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

STUDY NO. : 0342

## URINALYSIS

ANIMAL : RAT F344/DuCrj

MEASURE. TIME : 1

SEX : MALE

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+	
0 ppm	40	0	1	2	5	26	6	0		0	0	0	1	13	26		40	0	0	0	0	0		36	3	1	0	0	0		39	1	0	0	
3 ppm	42	0	2	4	8	25	3	0		0	0	0	4	10	28		42	0	0	0	0	0		40	1	1	0	0	0		40	2	0	0	
10 ppm	38	0	0	2	4	21	9	2		0	0	0	1	12	25		38	0	0	0	0	0		38	0	0	0	0	0		38	0	0	0	
30 ppm	23	0	1	5	2	9	6	0		0	0	0	0	3	20		23	0	0	0	0	0		20	2	1	0	0	0		22	1	0	0	

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

Test of CHI SQUARE

(HCL101)

BAIS 3

STUDY NO. : 0342  
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+
0 ppm	40	40	0	0	0	0		40	0	0	0
3 ppm	42	40	0	1	0	1		42	0	0	0
10 ppm	38	38	0	0	0	0		38	0	0	0
30 ppm	23	19	1	0	0	3	*	23	0	0	0

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

Test of CHI SQUARE

(HCL101)

BAIS 3

## APPENDIX F 2

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

STUDY NO. : 0342

ANIMAL : RAT F344/DuCrj

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

## URINALYSIS

PAGE : 3

Group Name	NO. of Animals	pH							CHI	Protein						CHI	Glucose						CHI	Ketone body						CHI	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+	
0 ppm	41	0	0	1	7	10	17	6		1	3	7	10	14	6		41	0	0	0	0	0		35	4	1	1	0	0		40	1	0	0	
3 ppm	38	0	0	3	4	12	18	1		0	1	7	12	8	10		38	0	0	0	0	0		31	5	2	0	0	0		38	0	0	0	
10 ppm	39	0	0	0	6	12	21	0		0	3	2	8	19	7		39	0	0	0	0	0		24	15	0	0	0	0	*	39	0	0	0	
30 ppm	32	0	1	2	3	11	10	5		0	0	2	7	16	7		32	0	0	0	0	0		18	13	1	0	0	0	*	31	1	0	0	

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

Test of CHI SQUARE

(HCL101)

BAIS 3

STUDY NO. : 0342

URINALYSIS

ANIMAL : RAT F344/DuCrj

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Occult blood					Urobilinogen						
		-	±	+	2+	3+	CHI	±	+	2+	3+	4+	CHI
0 ppm	41	41	0	0	0	0		41	0	0	0	0	
3 ppm	38	36	0	0	2	0		38	0	0	0	0	
10 ppm	39	36	2	0	1	0		39	0	0	0	0	
30 ppm	32	29	1	0	0	2		32	0	0	0	0	

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

Test of CHI SQUARE

(HCL101)

BAIS 3

## APPENDIX G 1

GROSS FINDINGS : SUMMARY, RAT : MALE

ALL ANIMALS

(2-YEAR STUDY)



STUDY NO. : 0342  
 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	0 ppm		3 ppm		10 ppm		30 ppm	
			50	(%)	50	(%)	50	(%)	50	(%)
skin/app	nodule		3	( 6)	4	( 8)	5	( 10)	12	( 24)
	scab		0	( 0)	1	( 2)	0	( 0)	0	( 0)
subcutis	edema		0	( 0)	0	( 0)	1	( 2)	0	( 0)
	jaundice		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	nodule		1	( 2)	0	( 0)	0	( 0)	0	( 0)
	mass		10	( 20)	8	( 16)	11	( 22)	14	( 28)
lung	red		1	( 2)	0	( 0)	0	( 0)	1	( 2)
	white zone		0	( 0)	1	( 2)	4	( 8)	2	( 4)
	red zone		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	yellow zone		0	( 0)	1	( 2)	0	( 0)	0	( 0)
	red patch		0	( 0)	1	( 2)	0	( 0)	1	( 2)
	nodule		5	( 10)	2	( 4)	0	( 0)	0	( 0)
	voluminous		0	( 0)	0	( 0)	0	( 0)	1	( 2)
lymph node	enlarged		2	( 4)	0	( 0)	0	( 0)	1	( 2)
spleen	enlarged		9	( 18)	3	( 6)	3	( 6)	4	( 8)
	white zone		0	( 0)	0	( 0)	1	( 2)	1	( 2)
	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	deformed		0	( 0)	1	( 2)	0	( 0)	0	( 0)
heart	white zone		0	( 0)	0	( 0)	1	( 2)	0	( 0)
	fluid:red		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	fluid:brown		0	( 0)	0	( 0)	0	( 0)	1	( 2)
salivary gl	nodule		0	( 0)	0	( 0)	2	( 4)	0	( 0)

STUDY NO. : 0342  
 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	0 ppm		3 ppm		10 ppm		30 ppm	
			50	(%)	50	(%)	50	(%)	50	(%)
forestomach	nodule		0	( 0)	0	( 0)	1	( 2)	0	( 0)
	ulcer		1	( 2)	0	( 0)	0	( 0)	1	( 2)
gl stomach	black zone		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	ulcer		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	erosion		1	( 2)	0	( 0)	0	( 0)	0	( 0)
stomach	nodule		0	( 0)	1	( 2)	0	( 0)	0	( 0)
small intes	red zone		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 2)
liver	enlarged		0	( 0)	0	( 0)	1	( 2)	0	( 0)
	pale		1	( 2)	0	( 0)	0	( 0)	0	( 0)
	nodule		1	( 2)	3	( 6)	1	( 2)	0	( 0)
	rough		5	( 10)	1	( 2)	2	( 4)	3	( 6)
	herniation		5	( 10)	9	( 18)	6	( 12)	3	( 6)
pancreas	nodule		2	( 4)	0	( 0)	0	( 0)	0	( 0)
kidney	enlarged		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	cyst		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	granular		18	( 36)	19	( 38)	20	( 40)	16	( 32)
urin bladd	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	urine:marked retention		1	( 2)	0	( 0)	0	( 0)	1	( 2)
pituitary	enlarged		2	( 4)	4	( 8)	1	( 2)	4	( 8)
	red zone		3	( 6)	3	( 6)	3	( 6)	1	( 2)
	nodule		4	( 8)	5	( 10)	3	( 6)	7	( 14)

STUDY NO. : 0342  
 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	0 ppm		3 ppm		10 ppm		30 ppm	
			50	(%)	50	(%)	50	(%)	50	(%)
thyroid	enlarged		3	( 6)	2	( 4)	2	( 4)	6	( 12)
adrenal	enlarged		1	( 2)	1	( 2)	2	( 4)	1	( 2)
testis	atrophic		0	( 0)	0	( 0)	3	( 6)	1	( 2)
	nodule		38	( 76)	39	( 78)	41	( 82)	44	( 88)
brain	red zone		0	( 0)	0	( 0)	1	( 2)	1	( 2)
	hemorrhage		0	( 0)	1	( 2)	0	( 0)	0	( 0)
	deformed		0	( 0)	0	( 0)	0	( 0)	1	( 2)
spinal cord	hemorrhage		0	( 0)	1	( 2)	0	( 0)	0	( 0)
eye	turbid		0	( 0)	0	( 0)	0	( 0)	2	( 4)
	white		3	( 6)	0	( 0)	1	( 2)	2	( 4)
	red		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 2)
Zymbal gl	nodule		0	( 0)	3	( 6)	1	( 2)	2	( 4)
muscle	nodule		0	( 0)	0	( 0)	1	( 2)	0	( 0)
bone	nodule		0	( 0)	1	( 2)	0	( 0)	0	( 0)
peritoneum	nodule		2	( 4)	5	( 10)	9	( 18)	18	( 36)
	thick		0	( 0)	0	( 0)	0	( 0)	1	( 2)
retroperit	mass		0	( 0)	0	( 0)	1	( 2)	1	( 2)
	cyst		0	( 0)	0	( 0)	1	( 2)	0	( 0)
abdominal c	hemorrhage		0	( 0)	0	( 0)	1	( 2)	0	( 0)
	pleural fluid		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	ascites		1	( 2)	1	( 2)	5	( 10)	11	( 22)

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 4

Organ	Findings	Group Name NO. of Animals	0 ppm		3 ppm		10 ppm		30 ppm	
			50	(%)	50	(%)	50	(%)	50	(%)
mesenterium	mass		1	( 2)	0	( 0)	0	( 0)	0	( 0)
thoracic ca	hemorrhage		0	( 0)	0	( 0)	1	( 2)	0	( 0)
	nodule		0	( 0)	0	( 0)	1	( 2)	0	( 0)
	pleural fluid		2	( 4)	0	( 0)	1	( 2)	3	( 6)
	ascites		0	( 0)	0	( 0)	0	( 0)	1	( 2)
other	ear:nodule		2	( 4)	0	( 0)	0	( 0)	0	( 0)
	hindlimb:nodule		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	nose:elevated		0	( 0)	0	( 0)	0	( 0)	6	( 12)
	nose:nodule		0	( 0)	0	( 0)	0	( 0)	1	( 2)
whole body	anemic		0	( 0)	1	( 2)	1	( 2)	0	( 0)

(HPT080)

BAIS 3

## APPENDIX G 2

GROSS FINDINGS : SUMMARY, RAT : MALE

DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0342  
 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	0 ppm		3 ppm		10 ppm		30 ppm	
			10	(%)	8	(%)	12	(%)	27	(%)
skin/app	nodule		0	( 0)	0	( 0)	2	( 17)	5	( 19)
subcutis	edema		0	( 0)	0	( 0)	1	( 8)	0	( 0)
	jaundice		0	( 0)	0	( 0)	0	( 0)	1	( 4)
	mass		3	( 30)	1	( 13)	4	( 33)	5	( 19)
lung	red		1	( 10)	0	( 0)	0	( 0)	1	( 4)
	white zone		0	( 0)	0	( 0)	1	( 8)	0	( 0)
	red zone		0	( 0)	0	( 0)	0	( 0)	1	( 4)
	yellow zone		0	( 0)	1	( 13)	0	( 0)	0	( 0)
	red patch		0	( 0)	1	( 13)	0	( 0)	1	( 4)
	nodule		0	( 0)	1	( 13)	0	( 0)	0	( 0)
	voluminus		0	( 0)	0	( 0)	0	( 0)	1	( 4)
lymph node	enlarged		2	( 20)	0	( 0)	0	( 0)	1	( 4)
spleen	enlarged		7	( 70)	2	( 25)	2	( 17)	3	( 11)
	white zone		0	( 0)	0	( 0)	1	( 8)	0	( 0)
	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 4)
heart	white zone		0	( 0)	0	( 0)	1	( 8)	0	( 0)
	fluid:red		0	( 0)	0	( 0)	0	( 0)	1	( 4)
	fluid:brown		0	( 0)	0	( 0)	0	( 0)	1	( 4)
salivary gl	nodule		0	( 0)	0	( 0)	1	( 8)	0	( 0)
forestomach	nodule		0	( 0)	0	( 0)	1	( 8)	0	( 0)
	ulcer		1	( 10)	0	( 0)	0	( 0)	1	( 4)
gl stomach	black zone		0	( 0)	0	( 0)	0	( 0)	1	( 4)

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 2

Organ	Findings	Group Name NO. of Animals	0 ppm		3 ppm		10 ppm		30 ppm	
			10	(%)	8	(%)	12	(%)	27	(%)
gl stomach	ulcer		0	( 0)	0	( 0)	0	( 0)	1	( 4)
	erosion		1	( 10)	0	( 0)	0	( 0)	0	( 0)
small intes	red zone		0	( 0)	0	( 0)	0	( 0)	1	( 4)
liver	enlarged		0	( 0)	0	( 0)	1	( 8)	0	( 0)
	pale		1	( 10)	0	( 0)	0	( 0)	0	( 0)
	nodule		0	( 0)	1	( 13)	0	( 0)	0	( 0)
	rough		1	( 10)	0	( 0)	1	( 8)	0	( 0)
	herniation		0	( 0)	3	( 38)	0	( 0)	3	( 11)
kidney	enlarged		0	( 0)	0	( 0)	0	( 0)	1	( 4)
	cyst		0	( 0)	0	( 0)	0	( 0)	1	( 4)
	granular		1	( 10)	0	( 0)	2	( 17)	1	( 4)
urin bladd	urine:marked retention		1	( 10)	0	( 0)	0	( 0)	1	( 4)
pituitary	enlarged		1	( 10)	0	( 0)	0	( 0)	2	( 7)
	nodule		1	( 10)	1	( 13)	1	( 8)	1	( 4)
thyroid	enlarged		0	( 0)	0	( 0)	0	( 0)	1	( 4)
adrenal	enlarged		0	( 0)	1	( 13)	1	( 8)	1	( 4)
testis	atrophic		0	( 0)	0	( 0)	2	( 17)	1	( 4)
	nodule		3	( 30)	2	( 25)	8	( 67)	23	( 85)
brain	red zone		0	( 0)	0	( 0)	1	( 8)	1	( 4)
	hemorrhage		0	( 0)	1	( 13)	0	( 0)	0	( 0)
	deformed		0	( 0)	0	( 0)	0	( 0)	1	( 4)
spinal cord	hemorrhage		0	( 0)	1	( 13)	0	( 0)	0	( 0)

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 3

Organ	Findings	Group Name NO. of Animals	0 ppm		3 ppm		10 ppm		30 ppm	
			10	(%)	8	(%)	12	(%)	27	(%)
eye	turbid		0	( 0)	0	( 0)	0	( 0)	1	( 4)
	white		0	( 0)	0	( 0)	0	( 0)	2	( 7)
Zymbal gl	nodule		0	( 0)	1	( 13)	1	( 8)	1	( 4)
muscle	nodule		0	( 0)	0	( 0)	1	( 8)	0	( 0)
bone	nodule		0	( 0)	1	( 13)	0	( 0)	0	( 0)
peritoneum	nodule		0	( 0)	1	( 13)	2	( 17)	13	( 48)
	thick		0	( 0)	0	( 0)	0	( 0)	1	( 4)
retroperit	mass		0	( 0)	0	( 0)	0	( 0)	1	( 4)
abdominal c	hemorrhage		0	( 0)	0	( 0)	1	( 8)	0	( 0)
	pleural fluid		0	( 0)	0	( 0)	0	( 0)	1	( 4)
	ascites		1	( 10)	0	( 0)	2	( 17)	10	( 37)
mesenterium	mass		1	( 10)	0	( 0)	0	( 0)	0	( 0)
thoracic ca	hemorrhage		0	( 0)	0	( 0)	1	( 8)	0	( 0)
	nodule		0	( 0)	0	( 0)	1	( 8)	0	( 0)
	pleural fluid		0	( 0)	0	( 0)	1	( 8)	3	( 11)
	ascites		0	( 0)	0	( 0)	0	( 0)	1	( 4)
other	ear:nodule		1	( 10)	0	( 0)	0	( 0)	0	( 0)
	hindlimb:nodule		0	( 0)	0	( 0)	0	( 0)	1	( 4)
	nose:elevated		0	( 0)	0	( 0)	0	( 0)	3	( 11)
	nose:nodule		0	( 0)	0	( 0)	0	( 0)	1	( 4)
whole body	anemic		0	( 0)	0	( 0)	1	( 8)	0	( 0)



## APPENDIX G 3

GROSS FINDINGS : SUMMARY, RAT : MALE

SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (105W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	0 ppm		3 ppm		10 ppm		30 ppm	
			40	(%)	42	(%)	38	(%)	23	(%)
skin/app	nodule		3	( 8)	4	( 10)	3	( 8)	7	( 30)
	scab		0	( 0)	1	( 2)	0	( 0)	0	( 0)
subcutis	nodule		1	( 3)	0	( 0)	0	( 0)	0	( 0)
	mass		7	( 18)	7	( 17)	7	( 18)	9	( 39)
lung	white zone		0	( 0)	1	( 2)	3	( 8)	2	( 9)
	nodule		5	( 13)	1	( 2)	0	( 0)	0	( 0)
spleen	enlarged		2	( 5)	1	( 2)	1	( 3)	1	( 4)
	white zone		0	( 0)	0	( 0)	0	( 0)	1	( 4)
	deformed		0	( 0)	1	( 2)	0	( 0)	0	( 0)
salivary gl	nodule		0	( 0)	0	( 0)	1	( 3)	0	( 0)
stomach	nodule		0	( 0)	1	( 2)	0	( 0)	0	( 0)
small intes	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 4)
liver	nodule		1	( 3)	2	( 5)	1	( 3)	0	( 0)
	rough		4	( 10)	1	( 2)	1	( 3)	3	( 13)
	herniation		5	( 13)	6	( 14)	6	( 16)	0	( 0)
pancreas	nodule		2	( 5)	0	( 0)	0	( 0)	0	( 0)
kidney	granular		17	( 43)	19	( 45)	18	( 47)	15	( 65)
urin bladd	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 4)
pituitary	enlarged		1	( 3)	4	( 10)	1	( 3)	2	( 9)
	red zone		3	( 8)	3	( 7)	3	( 8)	1	( 4)
	nodule		3	( 8)	4	( 10)	2	( 5)	6	( 26)
thyroid	enlarged		3	( 8)	2	( 5)	2	( 5)	5	( 22)

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (105W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	0 ppm		3 ppm		10 ppm		30 ppm	
			40	(%)	42	(%)	38	(%)	23	(%)
adrenal	enlarged		1	( 3)	0	( 0)	1	( 3)	0	( 0)
testis	atrophic		0	( 0)	0	( 0)	1	( 3)	0	( 0)
	nodule		35	( 88)	37	( 88)	33	( 87)	21	( 91)
eye	turbid		0	( 0)	0	( 0)	0	( 0)	1	( 4)
	white		3	( 8)	0	( 0)	1	( 3)	0	( 0)
	red		0	( 0)	0	( 0)	0	( 0)	1	( 4)
	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 4)
Zymbal gl	nodule		0	( 0)	2	( 5)	0	( 0)	1	( 4)
peritoneum	nodule		2	( 5)	4	( 10)	7	( 18)	5	( 22)
retroperit	mass		0	( 0)	0	( 0)	1	( 3)	0	( 0)
	cyst		0	( 0)	0	( 0)	1	( 3)	0	( 0)
abdominal c	ascites		0	( 0)	1	( 2)	3	( 8)	1	( 4)
thoracic ca	pleural fluid		2	( 5)	0	( 0)	0	( 0)	0	( 0)
other	ear:nodule		1	( 3)	0	( 0)	0	( 0)	0	( 0)
	nose:elevated		0	( 0)	0	( 0)	0	( 0)	3	( 13)
whole body	anemic		0	( 0)	1	( 2)	0	( 0)	0	( 0)

## APPENDIX G 4

GROSS FINDINGS : SUMMARY, RAT : FEMALE

ALL ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0342  
 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	0 ppm		3 ppm		10 ppm		30 ppm	
			50	(%)	50	(%)	49	(%)	50	(%)
skin/app	nodule		1	( 2)	0	( 0)	2	( 4)	4	( 8)
	scab		0	( 0)	0	( 0)	0	( 0)	1	( 2)
subcutis	jaundice		1	( 2)	0	( 0)	1	( 2)	1	( 2)
	nodule		0	( 0)	0	( 0)	1	( 2)	0	( 0)
	mass		9	( 18)	9	( 18)	19	( 39)	20	( 40)
lung	red		0	( 0)	1	( 2)	0	( 0)	0	( 0)
	white zone		0	( 0)	2	( 4)	2	( 4)	1	( 2)
	red zone		0	( 0)	1	( 2)	0	( 0)	2	( 4)
	brown zone		1	( 2)	0	( 0)	0	( 0)	0	( 0)
	nodule		0	( 0)	0	( 0)	2	( 4)	1	( 2)
lymph node	enlarged		0	( 0)	0	( 0)	2	( 4)	2	( 4)
spleen	enlarged		4	( 8)	5	( 10)	2	( 4)	9	( 18)
	nodule		0	( 0)	0	( 0)	1	( 2)	1	( 2)
heart	white zone		0	( 0)	0	( 0)	0	( 0)	1	( 2)
oral cavity	nodule		0	( 0)	0	( 0)	1	( 2)	0	( 0)
tongue	nodule		0	( 0)	1	( 2)	1	( 2)	1	( 2)
gl stomach	nodule		0	( 0)	0	( 0)	1	( 2)	0	( 0)
	ulcer		0	( 0)	2	( 4)	0	( 0)	0	( 0)
small intes	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	dilated		1	( 2)	0	( 0)	0	( 0)	0	( 0)
cecum	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 2)
liver	white zone		2	( 4)	2	( 4)	1	( 2)	0	( 0)

STUDY NO. : 0342  
 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	0 ppm	3 ppm	10 ppm	30 ppm
			50 (%)	50 (%)	49 (%)	50 (%)
liver	red zone		1 ( 2)	0 ( 0)	4 ( 8)	0 ( 0)
	nodule		1 ( 2)	0 ( 0)	0 ( 0)	1 ( 2)
	rough		2 ( 4)	3 ( 6)	1 ( 2)	2 ( 4)
	granular		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	nodular		0 ( 0)	1 ( 2)	1 ( 2)	0 ( 0)
	herniation		15 ( 30)	4 ( 8)	14 ( 29)	4 ( 8)
pancreas	nodule		1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)
kidney	white zone		0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)
	nodule		0 ( 0)	1 ( 2)	1 ( 2)	0 ( 0)
	cyst		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
	granular		0 ( 0)	3 ( 6)	1 ( 2)	3 ( 6)
urin bladd	nodule		0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
	urine:marked retention		0 ( 0)	0 ( 0)	1 ( 2)	1 ( 2)
pituitary	enlarged		7 ( 14)	8 ( 16)	5 ( 10)	3 ( 6)
	red zone		4 ( 8)	5 ( 10)	8 ( 16)	7 ( 14)
	black zone		0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)
	nodule		9 ( 18)	7 ( 14)	8 ( 16)	5 ( 10)
thyroid	enlarged		1 ( 2)	0 ( 0)	1 ( 2)	3 ( 6)
	nodule		1 ( 2)	0 ( 0)	0 ( 0)	1 ( 2)
adrenal	enlarged		1 ( 2)	2 ( 4)	1 ( 2)	0 ( 0)
	adhesion		0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)
ovary	enlarged		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 7

Organ	Findings	Group Name NO. of Animals	0 ppm		3 ppm		10 ppm		30 ppm	
			50	(%)	50	(%)	49	(%)	50	(%)
ovary	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	cyst		1	( 2)	3	( 6)	2	( 4)	1	( 2)
uterus	enlarged		0	( 0)	1	( 2)	0	( 0)	0	( 0)
	nodule		5	( 10)	10	( 20)	13	( 27)	11	( 22)
	cyst		1	( 2)	1	( 2)	1	( 2)	2	( 4)
vagina	fluid:red		0	( 0)	0	( 0)	0	( 0)	1	( 2)
brain	swollen		0	( 0)	0	( 0)	1	( 2)	0	( 0)
eye	turbid		1	( 2)	0	( 0)	1	( 2)	0	( 0)
	white		3	( 6)	2	( 4)	1	( 2)	0	( 0)
Zymbal gl	nodule		0	( 0)	0	( 0)	1	( 2)	0	( 0)
bone	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 2)
artculus	swollen		0	( 0)	0	( 0)	1	( 2)	0	( 0)
mediastinum	mass		1	( 2)	0	( 0)	0	( 0)	0	( 0)
peritoneum	nodule		0	( 0)	0	( 0)	1	( 2)	0	( 0)
	thick		0	( 0)	0	( 0)	0	( 0)	1	( 2)
abdominal c	hemorrhage		0	( 0)	2	( 4)	0	( 0)	0	( 0)
	mass		0	( 0)	0	( 0)	0	( 0)	2	( 4)
	ascites		0	( 0)	0	( 0)	0	( 0)	2	( 4)
thoracic ca	hemorrhage		1	( 2)	0	( 0)	0	( 0)	1	( 2)
	pleural fluid		0	( 0)	0	( 0)	0	( 0)	2	( 4)
other	ear:nodule		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	nose:elevated		0	( 0)	0	( 0)	0	( 0)	1	( 2)

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 8

Organ	Findings	Group Name NO. of Animals	0 ppm		3 ppm		10 ppm		30 ppm	
			50	(%)	50	(%)	49	(%)	50	(%)
whole body	anemic		0	( 0)	0	( 0)	0	( 0)	1	( 2)

(HPT080)

BAIS 3



## APPENDIX G 5

GROSS FINDINGS : SUMMARY, RAT : FEMALE

DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0342  
 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	0 ppm		3 ppm		10 ppm		30 ppm	
			9	(%)	12	(%)	10	(%)	18	(%)
skin/app	nodule		0	( 0)	0	( 0)	0	( 0)	2	( 11)
subcutis	jaundice		1	( 11)	0	( 0)	1	( 10)	1	( 6)
	mass		1	( 11)	2	( 17)	4	( 40)	4	( 22)
lung	red		0	( 0)	1	( 8)	0	( 0)	0	( 0)
	red zone		0	( 0)	1	( 8)	0	( 0)	1	( 6)
	nodule		0	( 0)	0	( 0)	1	( 10)	1	( 6)
lymph node	enlarged		0	( 0)	0	( 0)	2	( 20)	1	( 6)
spleen	enlarged		2	( 22)	4	( 33)	2	( 20)	6	( 33)
	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 6)
heart	white zone		0	( 0)	0	( 0)	0	( 0)	1	( 6)
tongue	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 6)
gl stomach	ulcer		0	( 0)	1	( 8)	0	( 0)	0	( 0)
liver	red zone		0	( 0)	0	( 0)	1	( 10)	0	( 0)
	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 6)
	rough		1	( 11)	2	( 17)	0	( 0)	0	( 0)
	granular		0	( 0)	0	( 0)	0	( 0)	1	( 6)
	herniation		1	( 11)	1	( 8)	5	( 50)	1	( 6)
pancreas	nodule		1	( 11)	1	( 8)	0	( 0)	0	( 0)
kidney	white zone		0	( 0)	0	( 0)	0	( 0)	1	( 6)
	nodule		0	( 0)	0	( 0)	1	( 10)	0	( 0)
urin bladd	urine:marked retention		0	( 0)	0	( 0)	1	( 10)	1	( 6)
pituitary	enlarged		3	( 33)	4	( 33)	2	( 20)	2	( 11)

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 5

Organ	Findings	Group Name NO. of Animals	0 ppm		3 ppm		10 ppm		30 ppm	
			9	(%)	12	(%)	10	(%)	18	(%)
pituitary	red zone		0	( 0)	0	( 0)	1	( 10)	1	( 6)
	black zone		0	( 0)	0	( 0)	0	( 0)	1	( 6)
	nodule		2	( 22)	0	( 0)	0	( 0)	0	( 0)
thyroid	enlarged		0	( 0)	0	( 0)	0	( 0)	1	( 6)
	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 6)
adrenal	enlarged		0	( 0)	1	( 8)	1	( 10)	0	( 0)
	adhesion		0	( 0)	0	( 0)	1	( 10)	0	( 0)
ovary	enlarged		0	( 0)	1	( 8)	0	( 0)	0	( 0)
	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 6)
	cyst		0	( 0)	1	( 8)	0	( 0)	0	( 0)
uterus	enlarged		0	( 0)	1	( 8)	0	( 0)	0	( 0)
	nodule		1	( 11)	3	( 25)	4	( 40)	7	( 39)
	cyst		0	( 0)	0	( 0)	0	( 0)	1	( 6)
vagina	fluid:red		0	( 0)	0	( 0)	0	( 0)	1	( 6)
brain	swollen		0	( 0)	0	( 0)	1	( 10)	0	( 0)
Zymbal gl	nodule		0	( 0)	0	( 0)	1	( 10)	0	( 0)
artculus	swollen		0	( 0)	0	( 0)	1	( 10)	0	( 0)
mediastinum	mass		1	( 11)	0	( 0)	0	( 0)	0	( 0)
peritoneum	thick		0	( 0)	0	( 0)	0	( 0)	1	( 6)
abdominal c	hemorrhage		0	( 0)	2	( 17)	0	( 0)	0	( 0)
	mass		0	( 0)	0	( 0)	0	( 0)	2	( 11)
	ascites		0	( 0)	0	( 0)	0	( 0)	2	( 11)

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 6

Organ	Findings	Group Name NO. of Animals	0 ppm		3 ppm		10 ppm		30 ppm	
			9	(%)	12	(%)	10	(%)	18	(%)
thoracic ca	hemorrhage		1	( 11)	0	( 0)	0	( 0)	0	( 0)
	pleural fluid		0	( 0)	0	( 0)	0	( 0)	1	( 6)
other	ear:nodule		0	( 0)	0	( 0)	0	( 0)	1	( 6)
	nose:elevated		0	( 0)	0	( 0)	0	( 0)	1	( 6)
whole body	anemic		0	( 0)	0	( 0)	0	( 0)	1	( 6)

(HPT080)

BAIS 3

## APPENDIX G 6

GROSS FINDINGS : SUMMARY, RAT : FEMALE

SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (105W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	0 ppm		3 ppm		10 ppm		30 ppm	
			41	(%)	38	(%)	39	(%)	32	(%)
skin/app	nodule		1	( 2)	0	( 0)	2	( 5)	2	( 6)
	scab		0	( 0)	0	( 0)	0	( 0)	1	( 3)
subcutis	nodule		0	( 0)	0	( 0)	1	( 3)	0	( 0)
	mass		8	( 20)	7	( 18)	15	( 38)	16	( 50)
lung	white zone		0	( 0)	2	( 5)	2	( 5)	1	( 3)
	red zone		0	( 0)	0	( 0)	0	( 0)	1	( 3)
	brown zone		1	( 2)	0	( 0)	0	( 0)	0	( 0)
	nodule		0	( 0)	0	( 0)	1	( 3)	0	( 0)
lymph node	enlarged		0	( 0)	0	( 0)	0	( 0)	1	( 3)
spleen	enlarged		2	( 5)	1	( 3)	0	( 0)	3	( 9)
	nodule		0	( 0)	0	( 0)	1	( 3)	0	( 0)
oral cavity	nodule		0	( 0)	0	( 0)	1	( 3)	0	( 0)
tongue	nodule		0	( 0)	1	( 3)	1	( 3)	0	( 0)
gl stomach	nodule		0	( 0)	0	( 0)	1	( 3)	0	( 0)
	ulcer		0	( 0)	1	( 3)	0	( 0)	0	( 0)
small intes	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 3)
	dilated		1	( 2)	0	( 0)	0	( 0)	0	( 0)
cecum	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 3)
liver	white zone		2	( 5)	2	( 5)	1	( 3)	0	( 0)
	red zone		1	( 2)	0	( 0)	3	( 8)	0	( 0)
	nodule		1	( 2)	0	( 0)	0	( 0)	0	( 0)
	rough		1	( 2)	1	( 3)	1	( 3)	2	( 6)

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 SACRIFICED ANIMALS (105W)

PAGE : 4

Organ	Findings	Group Name NO. of Animals	0 ppm		3 ppm		10 ppm		30 ppm	
			41	(%)	38	(%)	39	(%)	32	(%)
liver	nodular		0	( 0)	1	( 3)	1	( 3)	0	( 0)
	herniation		14	( 34)	3	( 8)	9	( 23)	3	( 9)
kidney	white zone		0	( 0)	0	( 0)	0	( 0)	2	( 6)
	nodule		0	( 0)	1	( 3)	0	( 0)	0	( 0)
	cyst		0	( 0)	1	( 3)	0	( 0)	0	( 0)
	granular		0	( 0)	3	( 8)	1	( 3)	3	( 9)
urin bladd	nodule		0	( 0)	0	( 0)	1	( 3)	0	( 0)
pituitary	enlarged		4	( 10)	4	( 11)	3	( 8)	1	( 3)
	red zone		4	( 10)	5	( 13)	7	( 18)	6	( 19)
	nodule		7	( 17)	7	( 18)	8	( 21)	5	( 16)
thyroid	enlarged		1	( 2)	0	( 0)	1	( 3)	2	( 6)
	nodule		1	( 2)	0	( 0)	0	( 0)	0	( 0)
adrenal	enlarged		1	( 2)	1	( 3)	0	( 0)	0	( 0)
ovary	cyst		1	( 2)	2	( 5)	2	( 5)	1	( 3)
uterus	nodule		4	( 10)	7	( 18)	9	( 23)	4	( 13)
	cyst		1	( 2)	1	( 3)	1	( 3)	1	( 3)
eye	turbid		1	( 2)	0	( 0)	1	( 3)	0	( 0)
	white		3	( 7)	2	( 5)	1	( 3)	0	( 0)
bone	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 3)
peritoneum	nodule		0	( 0)	0	( 0)	1	( 3)	0	( 0)
thoracic ca	hemorrhage		0	( 0)	0	( 0)	0	( 0)	1	( 3)
	pleural fluid		0	( 0)	0	( 0)	0	( 0)	1	( 3)

## APPENDIX H 1

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



STUDY NO. : 0342  
 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
0 ppm	40	376± 50	0.081± 0.024	3.360± 1.462	1.167± 0.098	1.421± 0.171	2.680± 0.224
3 ppm	42	384± 52	0.078± 0.013	3.577± 1.744	1.190± 0.107	1.391± 0.104	2.701± 0.240
10 ppm	38	365± 48	0.079± 0.015	4.051± 1.426	1.179± 0.121	1.400± 0.135	2.681± 0.275
30 ppm	23	313± 36**	0.076± 0.011	4.043± 1.752	1.177± 0.110	1.493± 0.306	2.779± 0.365

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

Test of Dunnett

(HCL040)

BAIS 3

STUDY NO. : 0342  
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	
0 ppm	40	1.041±	0.650	11.254±	2.244	1.955±	0.050
3 ppm	42	0.949±	0.268	11.201±	1.654	1.957±	0.061
10 ppm	38	0.913±	0.189	10.938±	1.569	1.940±	0.057
30 ppm	23	0.935±	0.458	10.865±	1.906	1.932±	0.070

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

Test of Dunnett

(HCL040)

BAIS 3

## APPENDIX H 2

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

STUDY NO. : 0342  
 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
0 ppm	41	249± 25	0.083± 0.032	0.127± 0.020	0.834± 0.067	1.014± 0.176	1.721± 0.112
3 ppm	38	251± 22	0.107± 0.179	0.151± 0.194	0.836± 0.054	0.990± 0.071	1.797± 0.270
10 ppm	39	252± 25	0.077± 0.010	0.129± 0.054	0.838± 0.061	0.978± 0.071	1.788± 0.147
30 ppm	32	235± 22*	0.076± 0.011	0.127± 0.048	0.854± 0.075	1.055± 0.187	1.874± 0.167***

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

Test of Dunnett

(HCL040)

BAIS 3

STUDY NO. : 0342  
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	
0 ppm	41	0.628±	0.840	6.434±	1.080	1.792±	0.057
3 ppm	38	0.611±	0.500	6.695±	0.890	1.785±	0.057
10 ppm	39	0.648±	0.972	6.507±	0.880	1.790±	0.050
30 ppm	32	0.836±	0.935*	6.593±	0.933	1.797±	0.048

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

Test of Dunnett

(HCL040)

BAIS 3

## APPENDIX I 1

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE  
UNIT: %

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

PAGE : 1

Group Name	NO. of Animals	Body Weight (g)	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS
0 ppm	40	376± 50	0.022± 0.007	0.917± 0.421	0.313± 0.031	0.381± 0.050	0.720± 0.080
3 ppm	42	384± 52	0.021± 0.004	0.943± 0.480	0.314± 0.045	0.367± 0.046	0.711± 0.079
10 ppm	38	365± 48	0.022± 0.005	1.140± 0.464	0.325± 0.027	0.387± 0.035	0.741± 0.080
30 ppm	23	313± 36**	0.025± 0.006*	1.282± 0.514**	0.382± 0.063**	0.482± 0.107**	0.898± 0.150**

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

Test of Dunnett

(HCL042)

BAIS 3

STUDY NO. : 0342  
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
0 ppm	40	0.279± 0.173	3.013± 0.601	0.527± 0.055
3 ppm	42	0.250± 0.080	2.937± 0.403	0.516± 0.052
10 ppm	38	0.255± 0.068	3.009± 0.370	0.539± 0.063
30 ppm	23	0.298± 0.135	3.488± 0.621**	0.626± 0.084**

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

Test of Dunnett

(HCL042)

BAIS 3



## APPENDIX I 2

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : FEMALE

(2-YEAR STUDY)

STUDY NO. : 0342  
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
0 ppm	41	249± 25	0.034± 0.020	0.051± 0.009	0.338± 0.033	0.411± 0.074	0.698± 0.067
3 ppm	38	251± 22	0.045± 0.084	0.061± 0.083	0.335± 0.029	0.397± 0.038	0.723± 0.141
10 ppm	39	252± 25	0.031± 0.004	0.052± 0.024	0.335± 0.024	0.391± 0.038	0.713± 0.080
30 ppm	32	235± 22*	0.033± 0.005	0.054± 0.019	0.366± 0.050**	0.453± 0.100*	0.803± 0.096**

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

Test of Dunnett

(HCL042)

BAIS 3

STUDY NO. : 0342  
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
0 ppm	41	0.252± 0.326	2.596± 0.392	0.728± 0.079
3 ppm	38	0.248± 0.222	2.683± 0.367	0.717± 0.061
10 ppm	39	0.255± 0.368	2.583± 0.225	0.717± 0.068
30 ppm	32	0.362± 0.410*	2.817± 0.423**	0.771± 0.075*

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. : 0342  
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 No. of Animals on Study Grade				0 ppm 50				3 ppm 50				10 ppm 50				30 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Integumentary system/appandage}																					
skin/app		<50>				<50>				<50>				<50>				<50>			
	inflammation	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 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 4 )	0 ( 0 )	0 ( 0 )
	hyperplasia:epidermis	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 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	scab	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	epidermal cyst	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
{Respiratory system}																					
nasal cavit		<50>				<50>				<50>				<50>				<50>			
	thrombus	0 ( 0 )	2 ( 4 )	2 ( 4 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	2 ( 4 )	0 ( 0 )	2 ( 4 )	2 ( 4 )	1 ( 2 )	0 ( 0 )	2 ( 4 )	2 ( 4 )	1 ( 2 )	0 ( 0 )	1 ( 2 )	1 ( 2 )	0 ( 0 )	0 ( 0 )
	mineralization	39 ( 78 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	37 ( 74 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	31 ( 62 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	41 ( 82 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	41 ( 82 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	squamous 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 )	2 ( 4 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	2 ( 4 )	2 ( 4 )	0 ( 0 )	0 ( 0 )

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

(HPT150)

BAIS3

STUDY NO. : 0342  
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 No. of Animals on Study Grade				0 ppm 50				3 ppm 50				10 ppm 50				30 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																					
nasal cavit		<50>				<50>				<50>				<50>				<50>			
	eosinophilic change:olfactory epithelium	24 ( 48)	17 ( 34)	3 ( 6)	0 ( 0)	28 ( 56)	15 ( 30)	2 ( 4)	0 ( 0)	19 ( 38)	16 ( 32)	5 ( 10)	0 ( 0)	33 ( 66)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	eosinophilic change:respiratory epithelium	19 ( 38)	1 ( 2)	0 ( 0)	0 ( 0)	27 ( 54)	0 ( 0)	0 ( 0)	0 ( 0)	29 ( 58)	0 ( 0)	0 ( 0)	0 ( 0)	17 ( 34)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	inflammation:foreign body	17 ( 34)	1 ( 2)	0 ( 0)	0 ( 0)	17 ( 34)	4 ( 8)	0 ( 0)	0 ( 0)	15 ( 30)	2 ( 4)	0 ( 0)	0 ( 0)	11 ( 22)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	inflammation:squamous epithelium	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	inflammation:respiratory epithelium	7 ( 14)	0 ( 0)	0 ( 0)	0 ( 0)	6 ( 12)	0 ( 0)	0 ( 0)	0 ( 0)	5 ( 10)	1 ( 2)	0 ( 0)	0 ( 0)	9 ( 18)	23 ( 46)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	respiratory metaplasia:olfactory epithelium	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	respiratory metaplasia:gland	41 ( 82)	0 ( 0)	0 ( 0)	0 ( 0)	48 ( 96)	0 ( 0)	0 ( 0)	0 ( 0)	48 ( 96)	0 ( 0)	0 ( 0)	0 ( 0)	44 ( 88)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	inflammation:transitional epithelium	9 ( 18)	0 ( 0)	0 ( 0)	0 ( 0)	15 ( 30)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 3

Organ_____	Findings_____	Group Name	0 ppm				3 ppm				10 ppm				30 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			<50>				<50>				<50>				<50>			
	squamous cell metaplasia:respiratory epithelium		1	0	0	0	2	0	0	0	3	0	0	0	1	0	1	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 2 )	( 0 )
	squamous cell metaplasia with atypia:respiratory epithelium		0	0	0	0	1	0	0	0	5	0	0	0	9	38	0	0 **
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 18 )	( 76 )	( 0 )	( 0 )
	squamous cell hyperplasia with atypia		0	0	0	0	0	0	0	0	0	0	0	0	15	15	0	0 **
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 30 )	( 30 )	( 0 )	( 0 )
	hyperplasia with atypia:respiratory epithelium		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 )	( 10 )	( 0 )	( 0 )	( 0 )
	hyperplasia with atypia:nasal gland		0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )
	hyperplasia with atypia:transitional epithelium		0	0	0	0	0	0	0	0	3	0	0	0	4	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )
	hyperplasia:transitional epithelium		0	0	0	0	0	0	0	0	11	0	0	0 **	5	1	0	0 *
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 22 )	( 0 )	( 0 )	( 0 )	( 10 )	( 2 )	( 0 )	( 0 )
	atrophy:olfactory epithelium		0	0	0	0	0	0	0	0	0	0	0	0	11	0	0	0 **
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 22 )	( 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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 4

Organ	Findings	Group Name No. of Animals on Study				0 ppm 50				3 ppm 50				10 ppm 50				30 ppm 50			
		Grade																			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																					
nasal cavit		<50>				<50>				<50>				<50>				<50>			
	necrosis:olfactory epithelium	0	0	0	0	1	0	0	0	0	0	0	0	3	0	0	0	3	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )
	necrosis:respiratory epithelium	0	0	0	0	0	0	0	0	1	0	0	0	4	2	1	0	4	2	1	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 8 )	( 4 )	( 2 )	( 0 )	( 8 )	( 4 )	( 2 )	( 0 )
	hyperplasia:respiratory epithelium	0	0	0	0	0	0	0	0	0	0	0	0	6	1	0	0 *	6	1	0	0 *
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 12 )	( 2 )	( 0 )	( 0 )	( 12 )	( 2 )	( 0 )	( 0 )
	thickening of bone:turbinate	0	0	0	0	3	0	0	0	24	14	0	0 **	15	6	0	0 **	15	6	0	0 **
		( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 48 )	( 28 )	( 0 )	( 0 )	( 30 )	( 12 )	( 0 )	( 0 )	( 30 )	( 12 )	( 0 )	( 0 )
larynx		<50>				<50>				<50>				<50>				<50>			
	inflammation	8	0	0	0	5	0	0	0	12	0	0	0	8	1	0	0	8	1	0	0
		( 16 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 24 )	( 0 )	( 0 )	( 0 )	( 16 )	( 2 )	( 0 )	( 0 )	( 16 )	( 2 )	( 0 )	( 0 )
lung		<50>				<50>				<50>				<50>				<50>			
	congestion	0	1	0	0	0	2	0	0	1	1	0	0	0	3	0	0	0	3	0	0
		( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )
	hemorrhage	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 5

		Group Name	0 ppm				3 ppm				10 ppm				30 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
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
lung			<50>				<50>				<50>				<50>			
	edema		0	0	0	0	0	1	0	0	1	1	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	perivascular inflammation		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 )
	accumulation of foamy cells		1	0	0	0	4	0	0	0	4	0	0	0	4	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )
	bronchiolar-alveolar cell hyperplasia		0	1	0	0	2	0	0	0	1	2	0	0	3	3	0	0
			( 0 )	( 2 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 2 )	( 4 )	( 0 )	( 0 )	( 6 )	( 6 )	( 0 )	( 0 )
	inflammation:foreign body		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 )
	hyperplasia:terminal bronchiole		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 )
{Hematopoietic system}																		
bone marrow			<50>				<50>				<50>				<50>			
	angiectasis		0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 6

Organ	Findings	Group Name No. of Animals on Study				0 ppm 50				3 ppm 50				10 ppm 50				30 ppm 50			
		Grade																			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																					
bone marrow		<50>				<50>				<50>				<50>				<50>			
	hemorrhage	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )
	granulation	7	0	0	0	3	0	0	0	2	1	0	0	1	0	0	0	1	0	0	0
		( 14 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 4 )	( 2 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	proliferation:histiocyte	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	increased hematopoiesis	5	0	0	0	2	0	0	0	3	0	0	0	3	0	0	0	4	0	0	0
		( 10 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )
	decreased hematopoiesis	0	0	0	0	0	0	0	0	2	0	0	0	2	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	erythropoiesis:increased	0	3	0	0	3	1	0	0	3	4	0	0	3	4	0	0	5	8	0	0 *
		( 0 )	( 6 )	( 0 )	( 0 )	( 6 )	( 2 )	( 0 )	( 0 )	( 6 )	( 8 )	( 0 )	( 0 )	( 6 )	( 8 )	( 0 )	( 0 )	( 10 )	( 16 )	( 0 )	( 0 )
	granulopoiesis:increased	0	0	0	0	1	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	hyperplasia:vascular	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 7

		Group Name No. of Animals on Study				0 ppm 50				3 ppm 50				10 ppm 50				30 ppm 50			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4			
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)			
{Hematopoietic system}																					
spleen			<50>				<50>				<50>				<50>						
	deposit of hemosiderin		17 ( 34)	1 ( 2)	0 ( 0)	0 ( 0)	4 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	0 ** ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	0 ** ( 0)	9 ( 18)	1 ( 2)	0 ( 0)	0 ( 0)	
	fibrosis		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	5 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	10 ( 20)	0 ( 0)	1 ( 2)	0 ** ( 0)	
	extramedullary hematopoiesis		18 ( 36)	3 ( 6)	1 ( 2)	0 ( 0)	29 ( 58)	2 ( 4)	3 ( 6)	0 ( 0)	0 ( 0)	23 ( 46)	7 ( 14)	3 ( 6)	0 ( 0)	0 ( 0)	19 ( 38)	9 ( 18)	6 ( 12)	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)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	
{Circulatory system}																					
heart			<50>				<50>				<50>				<50>						
	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)	0 ( 0)	3 ( 6)	0 ( 0)	0 ( 0)	
	inflammation		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	
	myocardial fibrosis		18 ( 36)	28 ( 56)	0 ( 0)	0 ( 0)	34 ( 68)	15 ( 30)	0 ( 0)	0 ( 0)	0 ** ( 0)	29 ( 58)	16 ( 32)	0 ( 0)	0 ( 0)	0 ( 0)	35 ( 70)	9 ( 18)	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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 8

Organ_____	Findings_____	Group Name	0 ppm				3 ppm				10 ppm				30 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
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Circulatory system}																		
artery/aort	mineralization		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	
	arteritis		0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
vein	thrombus		<50>				<50>				<50>				<50>			
			0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
{Digestive system}																		
tongue	inflammatory infiltration		<50>				<50>				<50>				<50>			
			1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	
	arteritis		1	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
salivary gl	atrophy		<50>				<50>				<50>				<50>			
			0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 9

Organ	Findings	Group Name No. of Animals on Study				0 ppm				3 ppm				10 ppm				30 ppm			
		Grade				50				50				50				50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																					
salivary gl	abscess	<50>				<50>				<50>				<50>				<50>			
		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
stomach	mineralization	<50>				<50>				<50>				<50>				<50>			
		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	erosion:forestomach	0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	ulcer:forestomach	0	2	1	0	0	0	0	0	0	2	1	0	1	1	1	0	1	1	1	0
		( 0 )	( 4 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 2 )	( 0 )	( 2 )	( 2 )	( 2 )	( 0 )	( 2 )	( 2 )	( 2 )	( 0 )
	hyperplasia:forestomach	0	2	1	0	0	2	0	0	2	1	2	0	1	3	0	0	1	3	0	0
		( 0 )	( 4 )	( 2 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 4 )	( 2 )	( 4 )	( 0 )	( 2 )	( 6 )	( 0 )	( 0 )	( 2 )	( 6 )	( 0 )	( 0 )
	erosion:glandular stomach	4	0	0	0	1	1	0	0	5	1	0	0	6	1	0	0	6	1	0	0
		( 8 )	( 0 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )	( 10 )	( 2 )	( 0 )	( 0 )	( 12 )	( 2 )	( 0 )	( 0 )	( 12 )	( 2 )	( 0 )	( 0 )
	ulcer:glandular stomach	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
liver	herniation	<50>				<50>				<50>				<50>				<50>			
		5	0	0	0	10	0	0	0	6	0	0	0	3	0	0	0	3	0	0	0
		( 10 )	( 0 )	( 0 )	( 0 )	( 20 )	( 0 )	( 0 )	( 0 )	( 12 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 10

Organ	Findings	0 ppm				3 ppm				10 ppm				30 ppm			
		50				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>			
	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	0	0	1	0	0	0	1	1	0	0	4	1	0	0
		( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 2)	( 2)	( 0)	( 0)	( 8)	( 2)	( 0)	( 0)
	necrosis:focal	2	1	0	0	2	0	0	0	2	2	0	0	2	0	0	0
		( 4)	( 2)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)	( 4)	( 4)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)
	fatty change	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)	( 4)	( 0)	( 0)	( 0)
	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)
	granulation	13	1	0	0	15	0	0	0	16	0	0	0	11	0	0	0
		( 26)	( 2)	( 0)	( 0)	( 30)	( 0)	( 0)	( 0)	( 32)	( 0)	( 0)	( 0)	( 22)	( 0)	( 0)	( 0)
	perivascular 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)
	extramedullary hematopoiesis	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)

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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 11

Organ	Findings	Group Name No. of Animals on Study Grade				0 ppm 50				3 ppm 50				10 ppm 50				30 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																					
liver		<50>				<50>				<50>				<50>				<50>			
	clear cell focus	4 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	3 ( 6 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	10 ( 20 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	3 ( 6 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	3 ( 6 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	acidophilic cell focus	6 ( 12 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	16 ( 32 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	4 ( 8 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	5 ( 10 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	5 ( 10 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	basophilic cell focus	3 ( 6 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	21 ( 42 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	16 ( 32 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	3 ( 6 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	3 ( 6 )	1 ( 2 )	0 ( 0 )	0 ( 0 )
	spongiosis hepatitis	5 ( 10 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	3 ( 6 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	3 ( 6 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	6 ( 12 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	6 ( 12 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	bile duct hyperplasia	48 ( 96 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	49 ( 98 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	47 ( 94 )	3 ( 6 )	0 ( 0 )	0 ( 0 )	44 ( 88 )	6 ( 12 )	0 ( 0 )	0 ( 0 )	44 ( 88 )	6 ( 12 )	0 ( 0 )	0 ( 0 )
	cholangiofibrosis	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 )	0 ( 0 )	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 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
pancreas		<50>				<49>				<50>				<50>				<50>			
	atrophy	3 ( 6 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	3 ( 6 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	4 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	4 ( 8 )	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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 12

Organ	Findings	Group Name No. of Animals on Study				0 ppm				3 ppm				10 ppm				30 ppm			
		Grade				50				50				50				50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4				
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																					
pancreas		<50>				<49>				<50>				<50>							
	islet cell hyperplasia	3	2	0	0	2	1	0	0	2	1	0	0	1	0	0	0	( 6 )	( 4 )	( 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	(	)	(	)
		(	)	(	)	(	)	(	)	(	)	(	)	(	)	(	)	(	)	(	)
	necrosis:focal	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	(	)	(	)
		(	)	(	)	(	)	(	)	(	)	(	)	(	)	(	)	(	)	(	)
	cyst	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	(	)	(	)
		(	)	(	)	(	)	(	)	(	)	(	)	(	)	(	)	(	)	(	)
	eosinophilic body	46	0	0	0	45	0	0	0	46	2	0	0	45	0	0	0	(	)	(	)
		(	)	(	)	(	)	(	)	(	)	(	)	(	)	(	)	(	)	(	)
	chronic nephropathy	13	23	13	0	10	19	18	0	8	23	18	0	9	18	20	0	(	)	(	)
		(	)	(	)	(	)	(	)	(	)	(	)	(	)	(	)	(	)	(	)
	hydronephrosis	0	0	0	0	0	0	0	0	0	0	0	0	1	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. : 0342  
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 No. of Animals on Study Grade				0 ppm 50				3 ppm 50				10 ppm 50				30 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																					
kidney	mineralization:cortico-medullary junction	<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 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	mineralization:papilla	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	mineralization:pelvis	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	mineralization:cortex	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
urin bladd	simple hyperplasia:transitional epithelium	<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 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )
	xanthogranuloma	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
{Endocrine system}																					
pituitary	angiectasis	<50>				0	0	0	0	2	0	0	0	1	0	0	0	3	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 14

Organ	Findings	Group Name No. of Animals on Study Grade				0 ppm 50				3 ppm 50				10 ppm 50				30 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																					
pituitary																					
	hemorrhage	<50>				0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	cyst	1	0	0	0	2	0	0	0	2	0	0	0	2	0	0	0	3	0	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )
	hyperplasia	11	2	0	0	7	2	0	0	6	5	0	0	6	5	0	0	1	1	0	0 **
		( 22 )	( 4 )	( 0 )	( 0 )	( 14 )	( 4 )	( 0 )	( 0 )	( 12 )	( 10 )	( 0 )	( 0 )	( 12 )	( 10 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )
	Rathke pouch	5	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0	2	1	0	0
		( 10 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 4 )	( 2 )	( 0 )	( 0 )
	focal hypertrophy	4	0	0	0	8	1	0	0	4	0	0	0	4	0	0	0	3	1	0	0
		( 8 )	( 0 )	( 0 )	( 0 )	( 16 )	( 2 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 6 )	( 2 )	( 0 )	( 0 )
thyroid																					
	ultimibranchial body remanet	<50>				1	0	0	0	0	0	0	0	2	0	0	0	2	0	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	C-cell hyperplasia	11	0	0	0	10	1	0	0	7	1	1	0	7	1	1	0	4	0	0	0
		( 22 )	( 0 )	( 0 )	( 0 )	( 20 )	( 2 )	( 0 )	( 0 )	( 14 )	( 2 )	( 2 )	( 0 )	( 14 )	( 2 )	( 2 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )
	focal follicular cell hyperplasia	4	0	0	0	0	1	0	0	3	0	0	0	3	0	0	0	3	2	0	0
		( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 6 )	( 4 )	( 0 )	( 0 )

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

STUDY NO. : 0342  
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				0 ppm 50				3 ppm 50				10 ppm 50				30 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																					
adrenal																					
	extramedullary hematopoiesis	<50>				<50>				<50>				<50>				<50>			
		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	hyperplasia:cortical cell	4	0	0	0	3	0	0	0	4	1	0	0	5	1	0	0	5	1	0	0
		( 8 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 8 )	( 2 )	( 0 )	( 0 )	( 10 )	( 2 )	( 0 )	( 0 )	( 10 )	( 2 )	( 0 )	( 0 )
	hyperplasia:medulla	6	0	0	0	5	0	0	0	2	2	0	0	5	0	0	0	5	0	0	0
		( 12 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 4 )	( 4 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )
	focal fatty change:cortex	9	1	1	0	12	1	0	0	7	0	0	0	10	1	0	0	10	1	0	0
		( 18 )	( 2 )	( 2 )	( 0 )	( 24 )	( 2 )	( 0 )	( 0 )	( 14 )	( 0 )	( 0 )	( 0 )	( 20 )	( 2 )	( 0 )	( 0 )	( 20 )	( 2 )	( 0 )	( 0 )
{Reproductive system}																					
testis																					
	atrophy	<50>				<50>				<50>				<50>				<50>			
		1	2	40	0	3	9	33	0	1	7	40	0	1	2	46	0	1	2	46	0
		( 2 )	( 4 )	( 80 )	( 0 )	( 6 )	( 18 )	( 66 )	( 0 )	( 2 )	( 14 )	( 80 )	( 0 )	( 2 )	( 4 )	( 92 )	( 0 )	( 2 )	( 4 )	( 92 )	( 0 )
	mineralization	5	0	0	0	4	1	0	0	7	0	0	0	2	0	0	0	2	0	0	0
		( 10 )	( 0 )	( 0 )	( 0 )	( 8 )	( 2 )	( 0 )	( 0 )	( 14 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	arteritis	2	1	0	0	2	0	0	0	0	2	0	0	0	1	0	0	0	1	0	0
		( 4 )	( 2 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )

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

STUDY NO. : 0342  
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 No. of Animals on Study Grade	0 ppm				3 ppm				10 ppm				30 ppm			
			50				50				50				50			
			1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)
{Reproductive system}																		
testis			<50>				<50>				<50>				<50>			
	interstitial cell hyperplasia		5 ( 10)	1 ( 2)	0 ( 0)	0 ( 0)	4 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
semin ves			<50>				<50>				<50>				<50>			
	inflammation		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)	0 ( 0)	0 ( 0)	0 ( 0)
prostate			<50>				<50>				<50>				<50>			
	inflammation		9 ( 18)	7 ( 14)	1 ( 2)	0 ( 0)	8 ( 16)	8 ( 16)	1 ( 2)	0 ( 0)	8 ( 16)	5 ( 10)	1 ( 2)	0 ( 0)	9 ( 18)	3 ( 6)	1 ( 2)	0 ( 0)
	hyperplasia		12 ( 24)	0 ( 0)	0 ( 0)	0 ( 0)	6 ( 12)	1 ( 2)	0 ( 0)	0 ( 0)	15 ( 30)	0 ( 0)	0 ( 0)	0 ( 0)	12 ( 24)	0 ( 0)	0 ( 0)	0 ( 0)
mammary gl			<50>				<50>				<50>				<50>			
	duct ectasia		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)
	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)
	galactoceles		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 8)	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. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 17

Organ	Findings	Group Name No. of Animals on Study				0 ppm				3 ppm				10 ppm				30 ppm			
		Grade				50				50				50				50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Nervous system}																					
brain		<50>				<50>				<50>				<50>				<50>			
	hemorrhage	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	necrosis:focal	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	gliosis	0	1	0	0	0	0	0	0	0	1	0	0	0	2	0	0	0	0	0	0
		( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	vacuolic change:nerve 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 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
spinal cord		<50>				<50>				<50>				<50>				<50>			
	gliosis	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
{Special sense organs/appendage}																					
eye		<50>				<50>				<50>				<50>				<50>			
	hemorrhage	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 18

		Group Name	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	50				50				50				50			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Special sense organs/appendage}																		
eye																		
	cataract		<50>				<50>				<50>				<50>			
			1	1	3	0	0	0	0	0	1	0	1	0	0	3	0	0
			( 2 )	( 2 )	( 6 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 2 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )
	retinal atrophy		45	0	2	0	46	0	0	0	40	0	1	0	34	0	2	0 *
			( 90 )	( 0 )	( 4 )	( 0 )	( 92 )	( 0 )	( 0 )	( 0 )	( 80 )	( 0 )	( 2 )	( 0 )	( 68 )	( 0 )	( 4 )	( 0 )
	keratitis		1	0	0	0	0	0	1	0	0	0	0	0	3	1	2	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 2 )	( 4 )	( 0 )
	iritis		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 )
Harder gl																		
	degeneration		<50>				<50>				<50>				<50>			
			3	2	0	0	4	1	0	0	2	0	0	0	5	1	0	0
			( 6 )	( 4 )	( 0 )	( 0 )	( 8 )	( 2 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 10 )	( 2 )	( 0 )	( 0 )
	lymphocytic infiltration		2	0	0	0	3	0	0	0	2	0	0	0	1	0	0	0
			( 4 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
Zymbal gl																		
	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 )

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. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 19

Organ	Findings	Group Name	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Musculoskeletal system}																		
muscle			<50>				<50>				<50>				<50>			
	atrophy		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
{Body cavities}																		
peritoneum			<50>				<50>				<50>				<50>			
	cyst		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	peritonitis		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 )
	mesothelial hyperplasia		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 )

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 2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : MALE : DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)



STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 1

		Group Name	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	10				8				12				27			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Integumentary system/appandage}																		
skin/app			<10>				< 8>				<12>				<27>			
	inflammation		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)	( 4)	( 0)	( 0)
	hyperplasia:epidermis		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)	( 4)	( 0)	( 0)	( 0)	
{Respiratory system}																		
nasal cavit			<10>				< 8>				<12>				<27>			
	thrombus		0	2	2	0	1	0	2	0	2	1	1	0	1	1	0	0 *
			( 0)	( 20)	( 20)	( 0)	( 13)	( 0)	( 25)	( 0)	( 17)	( 8)	( 8)	( 0)	( 4)	( 4)	( 0)	( 0)
	mineralization		9	0	0	0	6	0	0	0	8	0	0	0	23	0	0	0
			( 90)	( 0)	( 0)	( 0)	( 75)	( 0)	( 0)	( 0)	( 67)	( 0)	( 0)	( 0)	( 85)	( 0)	( 0)	( 0)
	eosinophilic change:olfactory epithelium		6	0	0	0	5	0	0	0	3	0	1	0	17	0	0	0
			( 60)	( 0)	( 0)	( 0)	( 63)	( 0)	( 0)	( 0)	( 25)	( 0)	( 8)	( 0)	( 63)	( 0)	( 0)	( 0)
eosinophilic change:respiratory epithelium		2	0	0	0	3	0	0	0	5	0	0	0	6	1	0	0	
		( 20)	( 0)	( 0)	( 0)	( 38)	( 0)	( 0)	( 0)	( 42)	( 0)	( 0)	( 0)	( 22)	( 4)	( 0)	( 0)	
inflammation:foreign body		1	0	0	0	2	3	0	0 *	5	0	0	0	10	0	0	0	
			( 10)	( 0)	( 0)	( 0)	( 25)	( 38)	( 0)	( 0)	( 42)	( 0)	( 0)	( 0)	( 37)	( 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. : 0342  
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	Group Name No. of Animals on Study Grade				0 ppm 10				3 ppm 8				10 ppm 12				30 ppm 27			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																					
nasal cavit		<10>				< 8>				<12>				<27>							
	inflammation:respiratory epithelium	1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 13)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 15)	12 ( 44)	0 ( 0)	0 ( 0)				
	respiratory metaplasia:olfactory epithelium	1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 7)	0 ( 0)	0 ( 0)	0 ( 0)				
	respiratory metaplasia:gland	6 ( 60)	0 ( 0)	0 ( 0)	0 ( 0)	7 ( 88)	0 ( 0)	0 ( 0)	0 ( 0)	11 ( 92)	0 ( 0)	0 ( 0)	0 ( 0)	22 ( 81)	0 ( 0)	0 ( 0)	0 ( 0)				
	inflammation:transitional epithelium	1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)				
	squamous cell metaplasia:respiratory epithelium	1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 13)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)	1 ( 4)	0 ( 0)				
	squamous cell metaplasia with atypia:respiratory epithelium	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 33)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 15)	21 ( 78)	0 ( 0)	0 ( 0)				
	squamous cell hyperplasia with atypia	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	10 ( 37)	9 ( 33)	0 ( 0)	0 ( 0)				
	hyperplasia with atypia:respiratory epithelium	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 11)	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. : 0342  
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	Group Name No. of Animals on Study Grade	0 ppm 10				3 ppm 8				10 ppm 12				30 ppm 27			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavit																		
	hyperplasia with atypia: nasal gland		<10>				< 8>				<12>				<27>			
			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 )	( 4 )	( 0 )	( 0 )
	hyperplasia with atypia: transitional epithelium		0	0	0	0	0	0	0	0	1	0	0	0	3	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )
	hyperplasia: transitional epithelium		0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 4 )	( 0 )	( 0 )
	atrophy: olfactory epithelium		0	0	0	0	0	0	0	0	0	0	0	0	7	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 26 )	( 0 )	( 0 )	( 0 )
	necrosis: olfactory epithelium		0	0	0	0	1	0	0	0	0	0	0	0	3	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )
	necrosis: respiratory epithelium		0	0	0	0	0	0	0	0	1	0	0	0	3	2	1	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 11 )	( 7 )	( 4 )	( 0 )
	hyperplasia: respiratory epithelium		0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )
	thickening of bone: turbinate		0	0	0	0	0	0	0	0	4	3	0	0 *	8	4	0	0 *
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 33 )	( 25 )	( 0 )	( 0 )	( 30 )	( 15 )	( 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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 4

Organ	Findings	Group Name No. of Animals on Study				0 ppm				3 ppm				10 ppm				30 ppm			
		Grade				10				8				12				27			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																					
larynx		<10>				< 8>				<12>				<27>							
	inflammation	1	0	0	0	1	0	0	0	1	0	0	0	3	0	0	0				
		( 10)	( 0)	( 0)	( 0)	( 13)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 11)	( 0)	( 0)	( 0)				
lung		<10>				< 8>				<12>				<27>							
	congestion	0	1	0	0	0	2	0	0	1	1	0	0	0	2	0	0				
		( 0)	( 10)	( 0)	( 0)	( 0)	( 25)	( 0)	( 0)	( 8)	( 8)	( 0)	( 0)	( 0)	( 7)	( 0)	( 0)				
	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)	( 4)	( 0)	( 0)				
	edema	0	0	0	0	0	1	0	0	1	1	0	0	0	0	0	0				
		( 0)	( 0)	( 0)	( 0)	( 0)	( 13)	( 0)	( 0)	( 8)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)				
	perivascular inflammation	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)	( 0)	( 0)	( 0)				
	accumulation of foamy cells	0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0				
		( 0)	( 0)	( 0)	( 0)	( 13)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)				
	bronchiolar-alveolar cell hyperplasia	0	0	0	0	0	0	0	0	0	1	0	0	2	2	0	0				
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 7)	( 7)	( 0)	( 0)				
	inflammation:foreign body	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)	( 4)	( 0)	( 0)				

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

STUDY NO. : 0342  
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	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	10				8				12				27			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
lung			<10>				< 8>				<12>				<27>			
	hyperplasia:terminal bronchiole		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 )	( 4 )	( 0 )	( 0 )	( 0 )
{Hematopoietic system}																		
bone marrow			<10>				< 8>				<12>				<27>			
	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 )	( 4 )	( 0 )	( 0 )
	proliferation:histiocyte		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 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	increased hematopoiesis		0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )
	decreased 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 )	( 4 )	( 0 )	( 0 )	( 0 )
	erythropoiesis:increased		0	3	0	0	2	0	0	0	2	3	0	0	2	8	0	0
			( 0 )	( 30 )	( 0 )	( 0 )	( 25 )	( 0 )	( 0 )	( 0 )	( 17 )	( 25 )	( 0 )	( 0 )	( 7 )	( 30 )	( 0 )	( 0 )
	granulopoiesis:increased		0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 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. : 0342  
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	Group Name		0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study		10				8				12				27			
		Grade		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
				(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																			
bone marrow	hyperplasia:vascular			<10>				< 8>				<12>				<27>			
				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 )	( 4 )	( 0 )	( 0 )	( 0 )
spleen	deposit of hemosiderin			<10>				< 8>				<12>				<27>			
				0	0	0	0	1	0	0	0	2	0	0	0	5	1	0	0
				( 0 )	( 0 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )	( 17 )	( 0 )	( 0 )	( 0 )	( 19 )	( 4 )	( 0 )	( 0 )
	fibrosis			0	0	0	0	0	0	0	0	1	0	0	0	3	0	1	0
				( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 11 )	( 0 )	( 4 )	( 0 )
	extramedullary hematopoiesis			0	2	1	0	3	0	2	0	1	3	3	0	7	6	6	0
				( 0 )	( 20 )	( 10 )	( 0 )	( 38 )	( 0 )	( 25 )	( 0 )	( 8 )	( 25 )	( 25 )	( 0 )	( 26 )	( 22 )	( 22 )	( 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 )	( 4 )	( 0 )	( 0 )	( 0 )
{Circulatory system}																			
heart	thrombus			<10>				< 8>				<12>				<27>			
				0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0
				( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 11 )	( 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. : 0342  
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 No. of Animals on Study Grade	0 ppm 10				3 ppm 8				10 ppm 12				30 ppm 27			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Circulatory system}																		
heart	inflammation		<10>				< 8>				<12>				<27>			
			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 )	( 7 )	( 0 )	( 0 )
	myocardial fibrosis		2	5	0	0	6	2	0	0 *	7	3	0	0	20	1	0	0 **
			( 20 )	( 50 )	( 0 )	( 0 )	( 75 )	( 25 )	( 0 )	( 0 )	( 58 )	( 25 )	( 0 )	( 0 )	( 74 )	( 4 )	( 0 )	( 0 )
artery/aort	mineralization		<10>				< 8>				<12>				<27>			
			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 )	( 4 )	( 0 )	( 0 )	( 0 )
	arteritis		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 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
vein	thrombus		<10>				< 8>				<12>				<27>			
			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 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
{Digestive system}																		
salivary gl	atrophy		<10>				< 8>				<12>				<27>			
			0	0	0	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 )

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

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

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

PAGE : 8

Organ	Findings	Group Name No. of Animals on Study Grade				0 ppm 10				3 ppm 8				10 ppm 12				30 ppm 27			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																					
salivary gl	abscess	<10>				< 8>				<12>				<27>							
		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
stomach	mineralization	<10>				< 8>				<12>				<27>							
		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	erosion:forestomach	<10>				< 8>				<12>				<27>							
		0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 13)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)
	ulcer:forestomach	<10>				< 8>				<12>				<27>							
		0	2	1	0	0	0	0	0	0	2	1	0	1	0	1	0	4	0	1	0
		( 0)	( 20)	( 10)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 17)	( 8)	( 0)	( 4)	( 0)	( 4)	( 0)	( 4)	( 0)	( 4)	( 0)
	hyperplasia:forestomach	<10>				< 8>				<12>				<27>							
		0	2	1	0	0	1	0	0	1	1	2	0	1	2	0	0	4	7	0	0
		( 0)	( 20)	( 10)	( 0)	( 0)	( 13)	( 0)	( 0)	( 8)	( 8)	( 17)	( 0)	( 4)	( 7)	( 0)	( 0)	( 4)	( 7)	( 0)	( 0)
	erosion:glandular stomach	<10>				< 8>				<12>				<27>							
		1	0	0	0	0	1	0	0	2	1	0	0	4	1	0	0	15	4	0	0
		( 10)	( 0)	( 0)	( 0)	( 0)	( 13)	( 0)	( 0)	( 17)	( 8)	( 0)	( 0)	( 15)	( 4)	( 0)	( 0)	( 15)	( 4)	( 0)	( 0)
	ulcer:glandular stomach	<10>				< 8>				<12>				<27>							
		0	0	0	0	1	0	0	0	0	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)
liver	herniation	<10>				< 8>				<12>				<27>							
		0	0	0	0	4	0	0	0 *	0	0	0	0	3	0	0	0	11	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 50)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 11)	( 0)	( 0)	( 0)	( 11)	( 0)	( 0)	( 0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe  
 < a > a : Number of animals examined at the site  
 b 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. : 0342  
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 No. of Animals on Study Grade				0 ppm 10				3 ppm 8				10 ppm 12				30 ppm 27			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																					
liver		<10>				< 8 >				<12>				<27>							
	necrosis:central	0	0	0	0	1	0	0	0	1	1	0	0	3	1	0	0				
		( 0 )	( 0 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )	( 8 )	( 8 )	( 0 )	( 0 )	( 11 )	( 4 )	( 0 )	( 0 )				
	necrosis:focal	0	0	0	0	0	0	0	0	2	2	0	0	2	0	0	0				
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 17 )	( 17 )	( 0 )	( 0 )	( 7 )	( 0 )	( 0 )	( 0 )				
	granulation	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0				
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )				
	extramedullary hematopoiesis	1	0	0	0	1	0	0	0	1	0	0	0	3	0	0	0				
		( 10 )	( 0 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )				
	clear 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 )	( 4 )	( 0 )	( 0 )	( 0 )				
	acidophilic cell focus	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 )	( 7 )	( 0 )	( 0 )	( 0 )				
	basophilic cell focus	0	0	0	0	2	0	0	0	1	0	0	0	1	1	0	0				
		( 0 )	( 0 )	( 0 )	( 0 )	( 25 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 4 )	( 4 )	( 0 )	( 0 )				
	spongiosis hepatitis	1	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0				
		( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 7 )	( 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. : 0342  
 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 No. of Animals on Study Grade	0 ppm 10				3 ppm 8				10 ppm 12				30 ppm 27			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
liver																		
	bile duct hyperplasia		<10>				< 8>				<12>				<27>			
			10	0	0	0	8	0	0	0	12	0	0	0	24	3	0	0
			(100)	( 0)	( 0)	( 0)	(100)	( 0)	( 0)	( 0)	(100)	( 0)	( 0)	( 0)	( 89)	( 11)	( 0)	( 0)
	cholangiofibrosis		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)
pancreas																		
	atrophy		<10>				< 8>				<12>				<27>			
			1	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0
			( 10)	( 0)	( 0)	( 0)	( 13)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)
	islet cell hyperplasia		2	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
			( 20)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)
{Urinary system}																		
kidney																		
	infarct		<10>				< 8>				<12>				<27>			
			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)
	necrosis:focal		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)	( 4)	( 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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 11

Organ	Findings	Group Name No. of Animals on Study Grade				0 ppm 10				3 ppm 8				10 ppm 12				30 ppm 27			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4				
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)				
{Urinary system}																					
kidney																					
	cyst	<10>				< 8>				<12>				<27>							
		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)	( 4)	( 0)	( 0)	( 0)				
	eosinophilic body	6	0	0	0	3	0	0	0	9	2	0	0	24	0	0	0				
		( 60)	( 0)	( 0)	( 0)	( 38)	( 0)	( 0)	( 0)	( 75)	( 17)	( 0)	( 0)	( 89)	( 0)	( 0)	( 0)				
	chronic nephropathy	4	3	2	0	4	1	0	0	1	8	2	0	8	10	6	0				
		( 40)	( 30)	( 20)	( 0)	( 50)	( 13)	( 0)	( 0)	( 8)	( 67)	( 17)	( 0)	( 30)	( 37)	( 22)	( 0)				
	hydronephrosis	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)	( 4)	( 0)	( 0)	( 0)				
	mineralization:cortico-medullary junction	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)				
	mineralization:pelvis	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0				
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 7)	( 0)	( 0)	( 0)				
	mineralization:cortex	0	0	0	0	2	0	0	0	0	0	0	0	1	0	0	0				
		( 0)	( 0)	( 0)	( 0)	( 25)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)				
urin bladd																					
	simple hyperplasia:transitional epithelium	<10>				< 8>				<12>				<27>							
		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)	( 4)	( 0)	( 0)				

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

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

PAGE : 12

		Group Name	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	10				8				12				27			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																		
pituitary	cyst		<10>				< 8>				<12>				<27>			
			0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	hyperplasia		1	0	0	0	2	0	0	0	1	1	0	0	0	0	0	0
			( 10 )	( 0 )	( 0 )	( 0 )	( 25 )	( 0 )	( 0 )	( 0 )	( 8 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	Rathke pouch		0	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 4 )	( 0 )	( 0 )
	focal hypertrophy		1	0	0	0	1	1	0	0	0	0	0	0	1	1	0	0
			( 10 )	( 0 )	( 0 )	( 0 )	( 13 )	( 13 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 4 )	( 0 )	( 0 )
thyroid	ultimibranhial body remanet		<10>				< 8>				<12>				<27>			
			1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	C-cell hyperplasia		1	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0
			( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	focal follicular cell hyperplasia		1	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0
			( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 4 )	( 0 )	( 0 )
adrenal	hyperplasia:cortical cell		<10>				< 8>				<12>				<27>			
			0	0	0	0	0	0	0	0	1	0	0	0	1	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 4 )	( 4 )	( 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. : 0342  
 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	0 ppm No. of Animals on Study Grade				3 ppm 8				10 ppm 12				30 ppm 27			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																	
adrenal		<10>				< 8>				<12>				<27>			
	hyperplasia:medulla	3 ( 30)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)	1 ( 8)	0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)
	focal fatty change:cortex	1 ( 10)	0 ( 0)	1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 17)	0 ( 0)	0 ( 0)	0 ( 0)	5 ( 19)	1 ( 4)	0 ( 0)	0 ( 0)
{Reproductive system}																	
testis		<10>				< 8>				<12>				<27>			
	atrophy	0 ( 0)	0 ( 0)	3 ( 30)	0 ( 0)	1 ( 13)	1 ( 13)	1 ( 13)	0 ( 0)	1 ( 8)	2 ( 17)	7 ( 58)	0 ( 0)	1 ( 4)	2 ( 7)	23 ( 85)	0 ** ( 0)
	mineralization	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 25)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 7)	0 ( 0)	0 ( 0)	0 ( 0)
	arteritis	0 ( 0)	1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	interstitial cell hyperplasia	2 ( 20)	1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)
prostate		<10>				< 8>				<12>				<27>			
	inflammation	2 ( 20)	0 ( 0)	1 ( 10)	0 ( 0)	1 ( 13)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)	1 ( 8)	1 ( 8)	0 ( 0)	2 ( 7)	1 ( 4)	1 ( 4)	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. : 0342  
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	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	10				8				12				27			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Reproductive system}																		
prostate	hyperplasia		<10>				< 8>				<12>				<27>			
			1	0	0	0	0	0	0	0	2	0	0	0	2	0	0	0
			( 10)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 17)	( 0)	( 0)	( 0)	( 7)	( 0)	( 0)	( 0)
mammary gl	duct ectasia		<10>				< 8>				<12>				<27>			
			1	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)
	galactocoele		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)	( 4)	( 0)	( 0)	( 0)
{Nervous system}																		
brain	hemorrhage		<10>				< 8>				<12>				<27>			
			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)
	necrosis:focal		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)	( 4)	( 0)	( 0)
	gliosis		0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 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 ≤ 0.05 \*\* : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 15

		Group Name	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	10				8				12				27			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Nervous system}																		
spinal cord			<10>				< 8>				<12>				<27>			
	gliosis		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
{Special sense organs/appendage}																		
eye			<10>				< 8>				<12>				<27>			
	hemorrhage		1	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)
	cataract		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)	( 7)	( 0)	( 0)
	retinal atrophy		7	0	0	0	4	0	0	0	6	0	0	0	12	0	2	0
			( 70)	( 0)	( 0)	( 0)	( 50)	( 0)	( 0)	( 0)	( 50)	( 0)	( 0)	( 0)	( 44)	( 0)	( 7)	( 0)
	keratitis		0	0	0	0	0	0	1	0	0	0	0	0	2	0	1	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 13)	( 0)	( 0)	( 0)	( 0)	( 0)	( 7)	( 0)	( 4)	( 0)
	iritis		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)	( 4)	( 0)	( 0)
Harder gl			<10>				< 8>				<12>				<27>			
	degeneration		1	2	0	0	0	1	0	0	1	0	0	0	4	1	0	0
			( 10)	( 20)	( 0)	( 0)	( 0)	( 13)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 15)	( 4)	( 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. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 16

Organ	Findings	Group Name No. of Animals on Study Grade	0 ppm 10				3 ppm 8				10 ppm 12				30 ppm 27			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Special sense organs/appendage}																		
Harder gl	lymphocytic infiltration		<10>				< 8>				<12>				<27>			
			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 )	( 4 )	( 0 )	( 0 )	( 0 )
{Musculoskeletal system}																		
muscle	atrophy		<10>				< 8>				<12>				<27>			
			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 )	( 4 )	( 0 )	( 0 )
{Body cavities}																		
peritoneum	mesothelial hyperplasia		<10>				< 8>				<12>				<27>			
			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 )	( 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 ≤ 0.05 \*\* : P ≤ 0.01 Test of Chi Square

(HPT150)

BAIS3



## APPENDIX J 3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : MALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 1

Organ	Findings	0 ppm 40				3 ppm 42				10 ppm 38				30 ppm 23			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Integumentary system/appandage}																	
skin/app		<40>				<42>				<38>				<23>			
	inflammation	0	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 )	( 4 )	( 0 )	( 0 )
	hyperplasia:epidermis	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 )
	scab	0	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	epidermal 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 )	( 4 )	( 0 )	( 0 )	( 0 )
{Respiratory system}																	
nasal cavit		<40>				<42>				<38>				<23>			
	thrombus	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 )
	mineralization	30	0	0	0	31	1	0	0	23	0	0	0	18	0	0	0
		( 75 )	( 0 )	( 0 )	( 0 )	( 74 )	( 2 )	( 0 )	( 0 )	( 61 )	( 0 )	( 0 )	( 0 )	( 78 )	( 0 )	( 0 )	( 0 )
	squamous cell hyperplasia	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 )	( 9 )	( 9 )	( 0 )	( 0 )

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

PAGE : 2

Organ_____	Findings_____	Group Name No. of Animals on Study				0 ppm 40				3 ppm 42				10 ppm 38				30 ppm 23			
		Grade																			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4				
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	
{Respiratory system}																					
nasal cavit		<40>				<42>				<38>				<23>							
	eosinophilic change:olfactory epithelium	18 ( 45)	17 ( 43)	3 ( 8)	0 ( 0)	23 ( 55)	15 ( 36)	2 ( 5)	0 ( 0)	16 ( 42)	16 ( 42)	4 ( 11)	0 ( 0)	16 ( 70)	2 ( 9)	0 ( 0)	0 ( 0)	0 ( 0)	**		
	eosinophilic change:respiratory epithelium	17 ( 43)	1 ( 3)	0 ( 0)	0 ( 0)	24 ( 57)	0 ( 0)	0 ( 0)	0 ( 0)	24 ( 63)	0 ( 0)	0 ( 0)	0 ( 0)	11 ( 48)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)			
	inflammation:foreign body	16 ( 40)	1 ( 3)	0 ( 0)	0 ( 0)	15 ( 36)	1 ( 2)	0 ( 0)	0 ( 0)	10 ( 26)	2 ( 5)	0 ( 0)	0 ( 0)	1 ( 4)	1 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	**		
	inflammation:squamous epithelium	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)			
	inflammation:respiratory epithelium	6 ( 15)	0 ( 0)	0 ( 0)	0 ( 0)	5 ( 12)	0 ( 0)	0 ( 0)	0 ( 0)	5 ( 13)	1 ( 3)	0 ( 0)	0 ( 0)	5 ( 22)	11 ( 48)	0 ( 0)	0 ( 0)	0 ( 0)	**		
	respiratory metaplasia:olfactory epithelium	2 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 7)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 9)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)			
	respiratory metaplasia:gland	35 ( 88)	0 ( 0)	0 ( 0)	0 ( 0)	41 ( 98)	0 ( 0)	0 ( 0)	0 ( 0)	37 ( 97)	0 ( 0)	0 ( 0)	0 ( 0)	22 ( 96)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)			
	inflammation:transitional epithelium	8 ( 20)	0 ( 0)	0 ( 0)	0 ( 0)	15 ( 36)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 8)	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

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REPORT TYPE : A1  
SEX : MALE

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

PAGE : 3

Organ	Findings	Group Name No. of Animals on Study Grade	0 ppm 40				3 ppm 42				10 ppm 38				30 ppm 23			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavit																		
	squamous cell metaplasia:respiratory epithelium		<40>				<42>				<38>				<23>			
			0	0	0	0	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 )
	squamous cell metaplasia with atypia:respiratory epithelium		0	0	0	0	1	0	0	0	1	0	0	0	5	17	0	0 **
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 22 )	( 74 )	( 0 )	( 0 )
	squamous cell hyperplasia with atypia		0	0	0	0	0	0	0	0	0	0	0	0	5	6	0	0 **
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 22 )	( 26 )	( 0 )	( 0 )
	hyperplasia with atypia:respiratory epithelium		0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 9 )	( 0 )	( 0 )	( 0 )
	hyperplasia with atypia:nasal gland		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 )	( 9 )	( 0 )	( 0 )
	hyperplasia with atypia:transitional 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 )	( 5 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	hyperplasia:transitional epithelium		0	0	0	0	0	0	0	0	11	0	0	0 **	4	0	0	0 *
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 29 )	( 0 )	( 0 )	( 0 )	( 17 )	( 0 )	( 0 )	( 0 )
	atrophy:olfactory epithelium		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 )	( 17 )	( 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. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 4

Organ	Findings	Group Name No. of Animals on Study Grade				0 ppm 40				3 ppm 42				10 ppm 38				30 ppm 23			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																					
nasal cavit		<40>				<42>				<38>				<23>							
	necrosis: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 )	( 4 )	( 0 )	( 0 )	( 0 )				
	hyperplasia:respiratory epithelium	0	0	0	0	0	0	0	0	0	0	0	0	3	1	0	0 *				
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 13 )	( 4 )	( 0 )	( 0 )				
	thickening of bone:turbinate	0	0	0	0	3	0	0	0	20	11	0	0 **	7	2	0	0 **				
		( 0 )	( 0 )	( 0 )	( 0 )	( 7 )	( 0 )	( 0 )	( 0 )	( 53 )	( 29 )	( 0 )	( 0 )	( 30 )	( 9 )	( 0 )	( 0 )				
larynx		<40>				<42>				<38>				<23>							
	inflammation	7	0	0	0	4	0	0	0	11	0	0	0	5	1	0	0				
		( 18 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 29 )	( 0 )	( 0 )	( 0 )	( 22 )	( 4 )	( 0 )	( 0 )				
lung		<40>				<42>				<38>				<23>							
	congestion	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 )	( 4 )	( 0 )	( 0 )				
	accumulation of foamy cells	1	0	0	0	3	0	0	0	4	0	0	0	3	0	0	0				
		( 3 )	( 0 )	( 0 )	( 0 )	( 7 )	( 0 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )				
	bronchiolar-alveolar cell hyperplasia	0	1	0	0	2	0	0	0	1	1	0	0	1	1	0	0				
		( 0 )	( 3 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 3 )	( 3 )	( 0 )	( 0 )	( 4 )	( 4 )	( 0 )	( 0 )				

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

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

b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 5

Organ	Findings	0 ppm 40				3 ppm 42				10 ppm 38				30 ppm 23			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																	
bone marrow																	
	angiectasis	<40>				<42>				<38>				<23>			
		0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	granulation	7	0	0	0	3	0	0	0	2	1	0	0	1	0	0	0
		( 18 )	( 0 )	( 0 )	( 0 )	( 7 )	( 0 )	( 0 )	( 0 )	( 5 )	( 3 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	increased hematopoiesis	5	0	0	0	2	0	0	0	3	0	0	0	1	0	0	0
		( 13 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	decreased hematopoiesis	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 )
	erythropoiesis:increased	0	0	0	0	1	1	0	0	1	1	0	0	3	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )	( 3 )	( 3 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )
spleen																	
	deposit of hemosiderin	<40>				<42>				<38>				<23>			
		17	1	0	0	3	0	0	0 **	0	0	0	0 **	4	0	0	0
		( 43 )	( 3 )	( 0 )	( 0 )	( 7 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 17 )	( 0 )	( 0 )	( 0 )
	fibrosis	0	0	0	0	5	0	0	0	2	0	0	0	7	0	0	0 **
		( 0 )	( 0 )	( 0 )	( 0 )	( 12 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 30 )	( 0 )	( 0 )	( 0 )
	extramedullary hematopoiesis	18	1	0	0	26	2	1	0	22	4	0	0	12	3	0	0
		( 45 )	( 3 )	( 0 )	( 0 )	( 62 )	( 5 )	( 2 )	( 0 )	( 58 )	( 11 )	( 0 )	( 0 )	( 52 )	( 13 )	( 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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 6

		Group Name	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	40				42				38				23			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Circulatory system}																		
heart			<40>				<42>				<38>				<23>			
	myocardial fibrosis		16	23	0	0	28	13	0	0 *	22	13	0	0	15	8	0	0
			( 40)	( 58)	( 0)	( 0)	( 67)	( 31)	( 0)	( 0)	( 58)	( 34)	( 0)	( 0)	( 65)	( 35)	( 0)	( 0)
artery/aort			<40>				<42>				<38>				<23>			
	arteritis		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)
{Digestive system}																		
tongue			<40>				<42>				<38>				<23>			
	inflammatory infiltration		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 3)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	arteritis		1	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
			( 3)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 5)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
stomach			<40>				<42>				<38>				<23>			
	ulcer:forestomach		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)	( 4)	( 0)	( 0)
	hyperplasia:forestomach		0	0	0	0	0	1	0	0	1	0	0	0	0	1	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)

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

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 7

Organ	Findings	Group Name No. of Animals on Study Grade				0 ppm 40				3 ppm 42				10 ppm 38				30 ppm 23			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																					
stomach		<40>				<42>				<38>				<23>							
	erosion:glandular stomach	3	0	0	0	1	0	0	0	3	0	0	0	2	0	0	0				
		( 8 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 9 )	( 0 )	( 0 )	( 0 )				
liver		<40>				<42>				<38>				<23>							
	herniation	5	0	0	0	6	0	0	0	6	0	0	0	0	0	0	0				
		( 13 )	( 0 )	( 0 )	( 0 )	( 14 )	( 0 )	( 0 )	( 0 )	( 16 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )				
	peliosis-like lesion	2	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0				
		( 5 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )				
	necrosis:central	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 )	( 4 )	( 0 )	( 0 )	( 0 )				
	necrosis:focal	2	1	0	0	2	0	0	0	0	0	0	0	0	0	0	0				
		( 5 )	( 3 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )				
	fatty change	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 )	( 9 )	( 0 )	( 0 )	( 0 )				
	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 )	( 4 )	( 0 )	( 0 )	( 0 )				
	granulation	13	1	0	0	15	0	0	0	16	0	0	0	10	0	0	0				
		( 33 )	( 3 )	( 0 )	( 0 )	( 36 )	( 0 )	( 0 )	( 0 )	( 42 )	( 0 )	( 0 )	( 0 )	( 43 )	( 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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 8

Organ	Findings	Group Name No. of Animals on Study Grade				0 ppm 40				3 ppm 42				10 ppm 38				30 ppm 23			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																					
liver		<40>				<42>				<38>				<23>							
	perivascular inflammation	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	extramedullary hematopoiesis	0	0	0	0	2	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	clear cell focus	4	0	0	0	3	1	0	0	10	0	0	0	2	0	0	0	2	0	0	0
		( 10 )	( 0 )	( 0 )	( 0 )	( 7 )	( 2 )	( 0 )	( 0 )	( 26 )	( 0 )	( 0 )	( 0 )	( 9 )	( 0 )	( 0 )	( 0 )	( 9 )	( 0 )	( 0 )	( 0 )
	acidophilic cell focus	6	1	0	0	16	1	0	0	4	1	0	0	3	0	0	0	3	0	0	0
		( 15 )	( 3 )	( 0 )	( 0 )	( 38 )	( 2 )	( 0 )	( 0 )	( 11 )	( 3 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )
	basophilic cell focus	3	1	0	0	19	0	0	0 **	15	2	0	0 **	2	0	0	0	2	0	0	0
		( 8 )	( 3 )	( 0 )	( 0 )	( 45 )	( 0 )	( 0 )	( 0 )	( 39 )	( 5 )	( 0 )	( 0 )	( 9 )	( 0 )	( 0 )	( 0 )	( 9 )	( 0 )	( 0 )	( 0 )
	spongiosis hepatitis	4	0	0	0	3	1	0	0	3	1	0	0	4	0	0	0	4	0	0	0
		( 10 )	( 0 )	( 0 )	( 0 )	( 7 )	( 2 )	( 0 )	( 0 )	( 8 )	( 3 )	( 0 )	( 0 )	( 17 )	( 0 )	( 0 )	( 0 )	( 17 )	( 0 )	( 0 )	( 0 )
	bile duct hyperplasia	38	2	0	0	41	1	0	0	35	3	0	0	20	3	0	0	20	3	0	0
		( 95 )	( 5 )	( 0 )	( 0 )	( 98 )	( 2 )	( 0 )	( 0 )	( 92 )	( 8 )	( 0 )	( 0 )	( 87 )	( 13 )	( 0 )	( 0 )	( 87 )	( 13 )	( 0 )	( 0 )
	cholangiofibrosis	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 9

		Group Name	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	40				42				38				23			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
liver	biliary cyst		<40>				<42>				<38>				<23>			
		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 3)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
pancreas	atrophy		<40>				<41>				<38>				<23>			
		2	0	0	0	0	2	0	0	0	2	0	0	0	3	0	0	0
			( 5)	( 0)	( 0)	( 0)	( 5)	( 0)	( 0)	( 0)	( 5)	( 0)	( 0)	( 0)	( 13)	( 0)	( 0)	( 0)
	islet cell hyperplasia		1	2	0	0	2	1	0	0	1	1	0	0	0	0	0	0
			( 3)	( 5)	( 0)	( 0)	( 5)	( 2)	( 0)	( 0)	( 3)	( 3)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
{Urinary system}																		
kidney	eosinophilic body		<40>				<42>				<38>				<23>			
		40	0	0	0	0	42	0	0	0	37	0	0	0	21	0	0	0
			(100)	( 0)	( 0)	( 0)	(100)	( 0)	( 0)	( 0)	( 97)	( 0)	( 0)	( 0)	( 91)	( 0)	( 0)	( 0)
	chronic nephropathy		9	20	11	0	6	18	18	0	7	15	16	0	1	8	14	0 *
			( 23)	( 50)	( 28)	( 0)	( 14)	( 43)	( 43)	( 0)	( 18)	( 39)	( 42)	( 0)	( 4)	( 35)	( 61)	( 0)
	mineralization:papilla		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. : 0342  
 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				0 ppm 40				3 ppm 42				10 ppm 38				30 ppm 23			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																					
kidney	mineralization:pelvis	<40>				<42>				<38>				<23>							
		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
urin bladd	xanthogranuloma	<40>				<42>				<38>				<23>							
		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
{Endocrine system}																					
pituitary	angiectasis	<40>				<42>				<38>				<23>							
		0	0	0	0	2	0	0	0	1	0	0	0	3	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 5)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)	( 13)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	hemorrhage	<40>				<42>				<38>				<23>							
		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	cyst	<40>				<42>				<38>				<23>							
		1	0	0	0	1	0	0	0	2	0	0	0	2	0	0	0	0	0	0	0
		( 3)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 5)	( 0)	( 0)	( 0)	( 9)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	hyperplasia	<40>				<42>				<38>				<23>							
		10	2	0	0	5	2	0	0	5	4	0	0	1	1	0	0	0	0	0	0
		( 25)	( 5)	( 0)	( 0)	( 12)	( 5)	( 0)	( 0)	( 13)	( 11)	( 0)	( 0)	( 4)	( 4)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

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

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 11

Organ	Findings	Group Name No. of Animals on Study Grade				0 ppm 40				3 ppm 42				10 ppm 38				30 ppm 23			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																					
pituitary		<40>				<42>				<38>				<23>							
	Rathke pouch	5 ( 13)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)				
	focal hypertrophy	3 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	7 ( 17)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 11)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 9)	0 ( 0)	0 ( 0)	0 ( 0)				
thyroid		<40>				<42>				<38>				<23>							
	ultimibranhial body remanet	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)				
	C-cell hyperplasia	10 ( 25)	0 ( 0)	0 ( 0)	0 ( 0)	10 ( 24)	1 ( 2)	0 ( 0)	0 ( 0)	7 ( 18)	1 ( 3)	0 ( 0)	0 ( 0)	3 ( 13)	0 ( 0)	0 ( 0)	0 ( 0)				
	focal follicular cell hyperplasia	3 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	3 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 9)	1 ( 4)	0 ( 0)	0 ( 0)				
adrenal		<40>				<42>				<38>				<23>							
	extramedullary hematopoiesis	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)				
	hyperplasia:cortical cell	4 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 7)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 8)	1 ( 3)	0 ( 0)	0 ( 0)	4 ( 17)	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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 12

Organ	Findings	Group Name No. of Animals on Study Grade	0 ppm 40				3 ppm 42				10 ppm 38				30 ppm 23			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																		
adrenal																		
	hyperplasia:medulla		<40>				<42>				<38>				<23>			
			3	0	0	0	5	0	0	0	1	1	0	0	4	0	0	0
			( 8 )	( 0 )	( 0 )	( 0 )	( 12 )	( 0 )	( 0 )	( 0 )	( 3 )	( 3 )	( 0 )	( 0 )	( 17 )	( 0 )	( 0 )	( 0 )
	focal fatty change:cortex		8	1	0	0	12	1	0	0	5	0	0	0	5	0	0	0
			( 20 )	( 3 )	( 0 )	( 0 )	( 29 )	( 2 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )	( 22 )	( 0 )	( 0 )	( 0 )
{Reproductive system}																		
testis																		
	atrophy		<40>				<42>				<38>				<23>			
			1	2	37	0	2	8	32	0	0	5	33	0	0	0	23	0
			( 3 )	( 5 )	( 93 )	( 0 )	( 5 )	( 19 )	( 76 )	( 0 )	( 0 )	( 13 )	( 87 )	( 0 )	( 0 )	( 0 )	( 100 )	( 0 )
	mineralization		5	0	0	0	4	1	0	0	4	0	0	0	0	0	0	0
			( 13 )	( 0 )	( 0 )	( 0 )	( 10 )	( 2 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	arteritis		2	0	0	0	2	0	0	0	0	2	0	0	0	1	0	0
			( 5 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )
	interstitial cell hyperplasia		3	0	0	0	4	0	0	0	1	0	0	0	0	0	0	0
			( 8 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
semin ves																		
	inflammation		<40>				<42>				<38>				<23>			
			0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 13

Organ	Findings	Group Name No. of Animals on Study Grade				0 ppm 40				3 ppm 42				10 ppm 38				30 ppm 23			
		1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)				
{Reproductive system}																					
prostate																					
	inflammation	<40>				<42>				<38>				<23>							
		7 ( 18)	7 ( 18)	0 ( 0)	0 ( 0)	7 ( 17)	8 ( 19)	1 ( 2)	0 ( 0)	7 ( 18)	4 ( 11)	0 ( 0)	0 ( 0)	7 ( 30)	2 ( 9)	0 ( 0)	0 ( 0)				
	hyperplasia	11 ( 28)	0 ( 0)	0 ( 0)	0 ( 0)	6 ( 14)	1 ( 2)	0 ( 0)	0 ( 0)	13 ( 34)	0 ( 0)	0 ( 0)	0 ( 0)	10 ( 43)	0 ( 0)	0 ( 0)	0 ( 0)				
mammary gl																					
	hyperplasia	<40>				<42>				<38>				<23>							
		0 ( 0)	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 ( 4)	0 ( 0)	0 ( 0)				
	galactoceles	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 13)	0 ( 0)	0 ( 0)	0 ( 0)				
{Nervous system}																					
brain																					
	gliosis	<40>				<42>				<38>				<23>							
		0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)				
	vacuolic change:nerve cell	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 ≤ 0.05 \*\* : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 14

		Group Name	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	40				42				38				23			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Special sense organs/appendage}																		
eye																		
	cataract		<40>				<42>				<38>				<23>			
			1	1	3	0	0	0	0	0	1	0	1	0	0	1	0	0
			( 3)	( 3)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 3)	( 0)	( 3)	( 0)	( 0)	( 4)	( 0)	( 0)
	retinal atrophy		38	0	2	0	42	0	0	0	34	0	1	0	22	0	0	0
			( 95)	( 0)	( 5)	( 0)	(100)	( 0)	( 0)	( 0)	( 89)	( 0)	( 3)	( 0)	( 96)	( 0)	( 0)	( 0)
	keratitis		1	0	0	0	0	0	0	0	0	0	0	0	1	1	1	0
			( 3)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 4)	( 4)	( 4)	( 0)
Harder gl																		
	degeneration		<40>				<42>				<38>				<23>			
			2	0	0	0	4	0	0	0	1	0	0	0	1	0	0	0
			( 5)	( 0)	( 0)	( 0)	(10)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)
	lymphocytic infiltration		2	0	0	0	3	0	0	0	2	0	0	0	0	0	0	0
			( 5)	( 0)	( 0)	( 0)	( 7)	( 0)	( 0)	( 0)	( 5)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
Zymbal gl																		
	inflammation		<40>				<42>				<38>				<23>			
			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)
{Body cavities}																		
peritoneum																		
	cyst		<40>				<42>				<38>				<23>			
			0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

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

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 15

Organ	Findings	Group Name No. of Animals on Study Grade	0 ppm 40				3 ppm 42				10 ppm 38				30 ppm 23			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

{Body cavities}

peritoneum

		<40>				<42>				<38>				<23>			
	peritonitis	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	mesothelial 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 )

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. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 20

Organ	Findings	Group Name No. of Animals on Study Grade	0 ppm 50				3 ppm 50				10 ppm 49				30 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Integumentary system/appandage}																		
skin/app	hyperplasia:epidermis		<50>				<50>				<49>				<50>			
			0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	scab		<50>				<50>				<49>				<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 )
subcutis	inflammation		<50>				<50>				<49>				<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 )
{Respiratory system}																		
nasal cavit	thrombus		<50>				<50>				<49>				<50>			
			0	0	1	0	0	0	1	0	0	1	1	0	0	0	0	0
			( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	mineralization		<50>				<50>				<49>				<50>			
			43	0	0	0	13	0	0	0 **	21	0	0	0 **	38	0	0	0
			( 86 )	( 0 )	( 0 )	( 0 )	( 26 )	( 0 )	( 0 )	( 0 )	( 43 )	( 0 )	( 0 )	( 0 )	( 76 )	( 0 )	( 0 )	( 0 )
	squamous cell hyperplasia		<50>				<50>				<49>				<50>			
			0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )

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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 21

Organ	Findings	Group Name No. of Animals on Study Grade				0 ppm 50				3 ppm 50				10 ppm 49				30 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																					
nasal cavit																					
	goblet cell hyperplasia	<50>				<50>				<49>				<50>							
		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	eosinophilic change:olfactory epithelium	10	29	10	0	1	18	30	0 **	2	27	20	0 *	9	37	3	0				
		( 20)	( 58)	( 20)	( 0)	( 2)	( 36)	( 60)	( 0)	( 4)	( 55)	( 41)	( 0)	( 18)	( 74)	( 6)	( 0)				
	eosinophilic change:respiratory epithelium	36	6	0	0	36	2	0	0	37	1	0	0	27	2	0	0 *				
		( 72)	( 12)	( 0)	( 0)	( 72)	( 4)	( 0)	( 0)	( 76)	( 2)	( 0)	( 0)	( 54)	( 4)	( 0)	( 0)				
	inflammation:foreign body	4	0	0	0	3	0	0	0	1	0	0	0	1	0	0	0				
		( 8)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)				
	inflammation:respiratory epithelium	1	0	0	0	1	0	0	0	3	0	0	0	21	5	0	0 **				
		( 2)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)	( 42)	( 10)	( 0)	( 0)				
	inflammation:olfactory epithelium	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0				
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)				
	respiratory metaplasia:olfactory epithelium	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0				
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)				
	respiratory metaplasia:gland	49	0	0	0	47	0	0	0	48	0	0	0	49	0	0	0				
		( 98)	( 0)	( 0)	( 0)	( 94)	( 0)	( 0)	( 0)	( 98)	( 0)	( 0)	( 0)	( 98)	( 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. : 0342  
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	0 ppm				3 ppm				10 ppm				30 ppm				
		No. of Animals on Study	50				50				49				50				
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	
{Respiratory system}																			
nasal cavit																			
	inflammation:transitional epithelium		6 ( 12)	1 ( 2)	0 ( 0)	0 ( 0)	16 ( 32)	0 ( 0)	0 ( 0)	0 ( 0)	0 * ( 0)	13 ( 27)	0 ( 0)	0 ( 0)	0 ( 0)	7 ( 14)	0 ( 0)	0 ( 0)	0 ( 0)
	squamous cell metaplasia:respiratory epithelium		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)	6 ( 12)	0 ( 0)	0 ( 0)	0 * ( 0)
	squamous cell metaplasia with atypia:respiratory epithelium		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)	10 ( 20)	26 ( 52)	0 ( 0)	0 ** ( 0)
	squamous cell hyperplasia with atypia		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	8 ( 16)	2 ( 4)	0 ( 0)	0 ** ( 0)
	hyperplasia:nasal gland		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	hyperplasia with atypia:nasal gland		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	hyperplasia with atypia:transitional epithelium		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)
	hyperplasia:transitional epithelium		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	8 ( 16)	0 ( 0)	0 ( 0)	0 ** ( 0)	13 ( 26)	2 ( 4)	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. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 23

		Group Name	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	50				50				49				50			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavit			<50>				<50>				<49>				<50>			
	atrophy:olfactory epithelium		0	0	0	0	0	0	0	0	0	0	0	0	12	1	0	0 **
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 24 )	( 2 )	( 0 )	( 0 )
	necrosis:olfactory epithelium		0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	necrosis:respiratory epithelium		0	0	0	0	0	0	0	0	2	0	0	0	3	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 6 )	( 2 )	( 0 )	( 0 )
	thickening of bone:turbinate		0	0	0	0	0	0	0	0	17	0	0	0 **	20	22	0	0 **
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 35 )	( 0 )	( 0 )	( 0 )	( 40 )	( 44 )	( 0 )	( 0 )
larynx			<50>				<50>				<49>				<50>			
	inflammation		13	0	0	0	11	0	0	0	15	2	0	0	13	0	0	0
			( 26 )	( 0 )	( 0 )	( 0 )	( 22 )	( 0 )	( 0 )	( 0 )	( 31 )	( 4 )	( 0 )	( 0 )	( 26 )	( 0 )	( 0 )	( 0 )
lung			<50>				<50>				<49>				<50>			
	congestion		0	4	0	0	0	7	0	0	0	2	0	0	0	0	0	0
			( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 14 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	hemorrhage		0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )

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

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

b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0342  
 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 No. of Animals on Study Grade				0 ppm 50				3 ppm 50				10 ppm 49				30 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																					
lung		<50>				<50>				<49>				<50>							
	edema	0	1	0	0	0	2	0	0	0	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 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	inflammation	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )
	foreign body granuloma	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	accumulation of foamy cells	2	0	0	0	5	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 4 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	interstitial pneumonia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )
	bronchiolar-alveolar cell hyperplasia	0	0	0	0	0	0	0	0	2	1	0	0	1	2	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 2 )	( 0 )	( 0 )	( 2 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
{Hematopoietic system}																					
bone marrow		<50>				<50>				<49>				<50>							
	granulation	8	2	0	0	6	2	0	0	5	3	0	0	5	0	0	0	0	0	0	0
		( 16 )	( 4 )	( 0 )	( 0 )	( 12 )	( 4 )	( 0 )	( 0 )	( 10 )	( 6 )	( 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  
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 ( c ) c : b / a \* 100

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

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 25

		Group Name No. of Animals on Study				3 ppm				10 ppm				30 ppm			
		50				50				49				50			
Organ	Findings	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																	
bone marrow		<50>				<50>				<49>				<50>			
	proliferation:histiocyte	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)
	increased hematopoiesis	4	1	0	0	2	1	0	0	2	0	0	0	6	2	0	0
		( 8)	( 2)	( 0)	( 0)	( 4)	( 2)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)	( 12)	( 4)	( 0)	( 0)
	myelofibrosis	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)
	erythropoiesis:increased	1	0	0	0	2	1	0	0	2	0	0	0	3	3	0	0
		( 2)	( 0)	( 0)	( 0)	( 4)	( 2)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)	( 6)	( 6)	( 0)	( 0)
	granulopoiesis:increased	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)	( 4)	( 0)	( 0)
thymus		<50>				<50>				<49>				<50>			
	cyst	2	0	0	0	3	0	0	0	0	0	0	0	2	0	0	0
		( 4)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)
spleen		<50>				<50>				<49>				<50>			
	deposit of hemosiderin	40	0	0	0	41	0	0	0	41	1	0	0	28	0	0	0 *
		( 80)	( 0)	( 0)	( 0)	( 82)	( 0)	( 0)	( 0)	( 84)	( 2)	( 0)	( 0)	( 56)	( 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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 26

Organ	Findings	Group Name No. of Animals on Study Grade	0 ppm 50				3 ppm 50				10 ppm 49				30 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																		
spleen			<50>				<50>				<49>				<50>			
	fibrosis		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 )
	extramedullary hematopoiesis		30	9	1	0	34	7	1	0	37	6	0	0	24	7	6	0
			( 60 )	( 18 )	( 2 )	( 0 )	( 68 )	( 14 )	( 2 )	( 0 )	( 76 )	( 12 )	( 0 )	( 0 )	( 48 )	( 14 )	( 12 )	( 0 )
{Circulatory system}																		
heart			<50>				<50>				<49>				<50>			
	thrombus		0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 2 )	( 0 )
	mineralization		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	inflammatory cell nest		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 )
	myocardial fibrosis		20	3	0	0	26	1	0	0	28	1	0	0	26	2	0	0
			( 40 )	( 6 )	( 0 )	( 0 )	( 52 )	( 2 )	( 0 )	( 0 )	( 57 )	( 2 )	( 0 )	( 0 )	( 52 )	( 4 )	( 0 )	( 0 )
artery/aort			<50>				<50>				<49>				<50>			
	arteritis		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



STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 27

Organ	Findings	Group Name No. of Animals on Study Grade	0 ppm 50				3 ppm 50				10 ppm 49				30 ppm 50			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
tooth	inflammation		<50>				<50>				<49>				<50>			
			0	0	0	0	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 )
tongue	arteritis		<50>				<50>				<49>				<50>			
			0	0	0	0	5	0	0	0	4	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
stomach	mineralization		<50>				<50>				<49>				<50>			
			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 )	( 0 )	( 0 )	( 0 )
	inflammatory infiltration		0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	erosion:forestomach		0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	ulcer:forestomach		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 )
	hyperplasia:forestomach		0	0	0	0	0	0	0	0	0	2	0	0	1	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )

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

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

PAGE : 28

Organ	Findings	Group Name No. of Animals on Study Grade				0 ppm 50				3 ppm 50				10 ppm 49				30 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																					
stomach		<50>				<50>				<49>				<50>							
	erosion:glandular stomach	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	hyperplasia:glandular stomach	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)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
small intes		<50>				<50>				<49>				<50>							
	erosion	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)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
liver		<50>				<50>				<49>				<50>							
	herniation	15 ( 30)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 8)	0 ( 0)	0 ( 0)	0 * ( 0)	14 ( 29)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	0 * ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	peliosis-like lesion	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	necrosis:central	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	necrosis:focal	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	5 ( 10)	1 ( 2)	0 ( 0)	0 ( 0)	4 ( 8)	1 ( 2)	0 ( 0)	0 ( 0)	6 ( 12)	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  
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HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 29

Organ	Findings	Group Name No. of Animals on Study Grade				0 ppm 50				3 ppm 50				10 ppm 49				30 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																					
liver		<50>				<50>				<49>				<50>							
	fatty change	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	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)
	inflammatory infiltration	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)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	lymphocytic infiltration	1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	granulation	28 ( 56)	2 ( 4)	0 ( 0)	0 ( 0)	22 ( 44)	6 ( 12)	1 ( 2)	0 ( 0)	23 ( 47)	4 ( 8)	0 ( 0)	0 ( 0)	12 ( 24)	4 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ** ( 0)
	organization	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	perivascular inflammation	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)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	fibrosis:focal	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	extramedullary hematopoiesis	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)

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

STUDY NO. : 0342  
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 No. of Animals on Study Grade				0 ppm 50				3 ppm 50				10 ppm 49				30 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																					
liver		<50>				<50>				<49>				<50>							
	clear cell focus	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	6 ( 12)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	acidophilic cell focus	2 ( 4)	2 ( 4)	0 ( 0)	0 ( 0)	2 ( 4)	1 ( 2)	0 ( 0)	0 ( 0)	5 ( 10)	1 ( 2)	0 ( 0)	0 ( 0)	6 ( 12)	1 ( 2)	0 ( 0)	0 ( 0)	6 ( 12)	1 ( 2)	0 ( 0)	0 ( 0)
	basophilic cell focus	34 ( 68)	3 ( 6)	0 ( 0)	0 ( 0)	29 ( 58)	9 ( 18)	0 ( 0)	0 ( 0)	33 ( 67)	4 ( 8)	0 ( 0)	0 ( 0)	30 ( 60)	4 ( 8)	0 ( 0)	0 ( 0)	30 ( 60)	4 ( 8)	0 ( 0)	0 ( 0)
	bile duct hyperplasia	33 ( 66)	0 ( 0)	0 ( 0)	0 ( 0)	31 ( 62)	1 ( 2)	0 ( 0)	0 ( 0)	36 ( 73)	1 ( 2)	0 ( 0)	0 ( 0)	29 ( 58)	0 ( 0)	0 ( 0)	0 ( 0)	29 ( 58)	0 ( 0)	0 ( 0)	0 ( 0)
	cholangiofibrosis	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
pancreas		<50>				<50>				<49>				<50>							
	atrophy	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)
	islet cell hyperplasia	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
{Urinary system}																					
kidney		<50>				<50>				<49>				<50>							
	infarct	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	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. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 31

Organ_____	Findings_____	Group Name No. of Animals on Study				0 ppm 50				3 ppm 50				10 ppm 49				30 ppm 50							
		Grade				1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4				
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)			
{Urinary system}																									
kidney		<50>				<50>				<49>				<50>											
	cyst	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)			
	hyaline droplet	48 ( 96)	0 ( 0)	0 ( 0)	0 ( 0)	48 ( 96)	0 ( 0)	0 ( 0)	0 ( 0)	46 ( 94)	0 ( 0)	0 ( 0)	0 ( 0)	48 ( 96)	0 ( 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)	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)	0 ( 0)			
	chronic nephropathy	32 ( 64)	6 ( 12)	0 ( 0)	0 ( 0)	25 ( 50)	9 ( 18)	6 ( 12)	0 ( 0)	26 ( 53)	10 ( 20)	3 ( 6)	0 ( 0)	28 ( 56)	10 ( 20)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)			
	hydronephrosis	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)			
	papillary necrosis	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)			
	mineralization:cortico-medullary junction	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)			
	mineralization:papilla	2 ( 4)	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)	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. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 32

		Group Name No. of Animals on Study Grade				0 ppm 50				3 ppm 50				10 ppm 49				30 ppm 50			
Organ_____	Findings_____	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)				
{Urinary system}																					
kidney		<50>				<50>				<49>				<50>							
	mineralization:pelvis	9 ( 18)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 * ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)				
	mineralization:cortex	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)				
	atypical tubule 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)				
urin bladd		<50>				<50>				<49>				<50>							
	simple hyperplasia:transitional epithelium	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)	1 ( 2)	0 ( 0)	0 ( 0)				
{Endocrine system}																					
pituitary		<50>				<50>				<49>				<50>							
	angiectasis	3 ( 6)	2 ( 4)	0 ( 0)	0 ( 0)	7 ( 14)	2 ( 4)	1 ( 2)	0 ( 0)	0 ( 0)	6 ( 12)	1 ( 2)	0 ( 0)	5 ( 10)	1 ( 2)	0 ( 0)	0 ( 0)				
	cyst	13 ( 26)	8 ( 16)	2 ( 4)	0 ( 0)	19 ( 38)	7 ( 14)	2 ( 4)	0 ( 0)	18 ( 37)	9 ( 18)	0 ( 0)	0 ( 0)	20 ( 40)	13 ( 26)	2 ( 4)	0 ( 0)				

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

STUDY NO. : 0342  
 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 No. of Animals on Study Grade				0 ppm 50				3 ppm 50				10 ppm 49				30 ppm 50			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																					
pituitary	hyperplasia	<50>				<50>				<49>				<50>							
		4	4	0	0	3	1	0	0	7	7	0	0	4	5	1	0				
		( 8)	( 8)	( 0)	( 0)	( 6)	( 2)	( 0)	( 0)	( 14)	( 14)	( 0)	( 0)	( 8)	( 10)	( 2)	( 0)				
	Rathke pouch	3	0	0	0	1	0	0	0	1	0	0	0	2	0	0	0				
		( 6)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)				
	focal hypertrophy	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)	( 4)	( 0)	( 0)	( 0)				
thyroid	ultimibranhial body remanet	<50>				<50>				<49>				<50>							
		0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0				
		( 0)	( 0)	( 0)	( 0)	( 2)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)				
	C-cell hyperplasia	12	1	0	0	8	2	0	0	13	0	0	0	9	0	0	0				
		( 24)	( 2)	( 0)	( 0)	( 16)	( 4)	( 0)	( 0)	( 27)	( 0)	( 0)	( 0)	( 18)	( 0)	( 0)	( 0)				
	focal follicular cell hyperplasia	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)				
adrenal	hemorrhage	<50>				<50>				<49>				<50>							
		0	0	0	0	0	1	1	0	0	1	0	0	0	0	0	0				
		( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 2)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 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. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 34

		Group Name	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	50				50				49				50			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																		
adrenal			<50>				<50>				<49>				<50>			
	peliosis-like lesion		23 ( 46)	19 ( 38)	1 ( 2)	0 ( 0)	28 ( 56)	11 ( 22)	0 ( 0)	0 ( 0)	29 ( 59)	7 ( 14)	0 ( 0)	0 * ( 0)	27 ( 54)	6 ( 12)	0 ( 0)	0 ** ( 0)
	cyst		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)	0 ( 0)	0 ( 0)	0 ( 0)
	extramedullary hematopoiesis		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	hyperplasia:cortical cell		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	1 ( 2)	5 ( 10)	0 ( 0)	0 ( 0)
	hyperplasia:medulla		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	1 ( 2)	0 ( 0)	0 ( 0)
	focal fatty change:cortex		8 ( 16)	2 ( 4)	0 ( 0)	0 ( 0)	12 ( 24)	1 ( 2)	0 ( 0)	0 ( 0)	11 ( 22)	6 ( 12)	0 ( 0)	0 ( 0)	10 ( 20)	10 ( 20)	1 ( 2)	0 * ( 0)
{Reproductive system}																		
ovary			<50>				<50>				<49>				<50>			
	cyst		1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)	1 ( 2)	2 ( 4)	0 ( 0)	0 ( 0)	1 ( 2)	2 ( 4)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)

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



STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 35

		Group Name	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	50				50				49				50			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Reproductive system}																		
uterus			<50>				<50>				<49>				<50>			
	dilatation		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 )
	hemorrhage		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 )
	inflammation		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	
	hyperplasia:epithelium		1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	hyperplasia:gland		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 )
	cystic endometrial hyperplasia		6	2	0	0	3	2	0	0	3	0	0	0	2	4	0	0
			( 12 )	( 4 )	( 0 )	( 0 )	( 6 )	( 4 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 4 )	( 8 )	( 0 )	( 0 )
vagina			<50>				<50>				<49>				<50>			
	squamous 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 )
mammary gl			<50>				<50>				<49>				<50>			
	hyperplasia		1	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 36

		Group Name	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	50				50				49				50			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Reproductive system}																		
mammary gl			<50>				<50>				<49>				<50>			
	galactoceles		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 )
{Nervous system}																		
brain			<50>				<50>				<49>				<50>			
	hemorrhage		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 )
	necrosis:focal		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	0	1	0	0	1	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )
	gliosis		0	0	0	0	2	0	0	0	0	0	0	0	0	3	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )
{Special sense organs/appendage}																		
eye			<50>				<50>				<49>				<50>			
	cataract		0	3	0	0	0	1	1	0	0	2	0	0	0	0	0	0
			( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 37

Organ_____	Findings_____	Group Name	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	50				50				49				50			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Special sense organs/appendage}																		
eye																		
	retinal atrophy		<50>				<50>				<49>				<50>			
			42	1	1	0	40	0	2	0	44	0	2	0	46	0	0	0
			( 84)	( 2)	( 2)	( 0)	( 80)	( 0)	( 4)	( 0)	( 90)	( 0)	( 4)	( 0)	( 92)	( 0)	( 0)	( 0)
	keratitis		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)
	iritis		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)	( 0)	( 0)
Harder gl																		
	degeneration		<50>				<50>				<49>				<50>			
			2	0	0	0	2	0	0	0	2	1	0	0	4	1	0	0
			( 4)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)	( 4)	( 2)	( 0)	( 0)	( 8)	( 2)	( 0)	( 0)
	lymphocytic infiltration		3	0	0	0	3	0	0	0	4	0	0	0	0	0	0	0
			( 6)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	granulation		3	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
			( 6)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	hyperplasia:mast cell		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)
nasolacr d																		
	inflammation		<50>				<50>				<49>				<50>			
			22	6	0	0	13	6	0	0	8	0	0	0 **	4	0	0	0 **
			( 44)	( 12)	( 0)	( 0)	( 26)	( 12)	( 0)	( 0)	( 16)	( 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. : 0342  
 ANIMAL : RAT F344/DuCrJ  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 38

Organ	Findings	Group Name No. of Animals on Study				0 ppm 50				3 ppm 50				10 ppm 49				30 ppm 50			
		Grade				1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
						(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

{Musculoskeletal system}

bone	osteosclerosis	<50>				3	1	1	0	6	0	0	0	2	1	0	0	9	2	0	0
		( 6 )	( 2 )	( 2 )	( 0 )	( 12 )	( 0 )	( 0 )	( 0 )	( 4 )	( 2 )	( 0 )	( 0 )	( 18 )	( 4 )	( 0 )	( 0 )	( 18 )	( 4 )	( 0 )	( 0 )
articulus	arthritis	<50>				0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

(HPT150)

BAIS3

## APPENDIX J 5

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : FEMALE : DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 17

Organ	Findings	Group Name No. of Animals on Study				0 ppm				3 ppm				10 ppm				30 ppm			
		Grade				9				12				10				18			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Integumentary system/appandage}																					
subcutis		< 9>				<12>				<10>				<18>							
	inflammation	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 11 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
{Respiratory system}																					
nasal cavit		< 9>				<12>				<10>				<18>							
	thrombus	0	0	1	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0	0	0
		( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	mineralization	6	0	0	0	6	0	0	0	8	0	0	0	11	0	0	0	0	0	0	0
		( 67 )	( 0 )	( 0 )	( 0 )	( 50 )	( 0 )	( 0 )	( 0 )	( 80 )	( 0 )	( 0 )	( 0 )	( 61 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	squamous cell 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 )	( 0 )	( 0 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	eosinophilic change:olfactory epithelium	4	3	1	0	1	8	2	0	1	7	2	0	6	10	1	0	0	0	0	0
		( 44 )	( 33 )	( 11 )	( 0 )	( 8 )	( 67 )	( 17 )	( 0 )	( 10 )	( 70 )	( 20 )	( 0 )	( 33 )	( 56 )	( 6 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	eosinophilic change:respiratory epithelium	5	0	0	0	4	0	0	0	5	0	0	0	6	0	0	0	0	0	0	0
		( 56 )	( 0 )	( 0 )	( 0 )	( 33 )	( 0 )	( 0 )	( 0 )	( 50 )	( 0 )	( 0 )	( 0 )	( 33 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	inflammation:respiratory epithelium	0	0	0	0	1	0	0	0	0	0	0	0	7	2	0	0 *	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 39 )	( 11 )	( 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. : 0342  
 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	Group Name No. of Animals on Study Grade				0 ppm 9				3 ppm 12				10 ppm 10				30 ppm 18			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																					
nasal cavit		< 9>				<12>				<10>				<18>							
	inflammation: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)	( 6)	( 0)	( 0)	( 0)				
	respiratory metaplasia:gland	8	0	0	0	10	0	0	0	9	0	0	0	18	0	0	0				
		( 89)	( 0)	( 0)	( 0)	( 83)	( 0)	( 0)	( 0)	( 90)	( 0)	( 0)	( 0)	(100)	( 0)	( 0)	( 0)				
	inflammation:transitional epithelium	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0				
		( 0)	( 0)	( 0)	( 0)	( 25)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)				
	squamous cell metaplasia:respiratory epithelium	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0				
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 11)	( 0)	( 0)	( 0)				
	squamous cell metaplasia with atypia:respiratory epithelium	0	0	0	0	0	0	0	0	1	0	0	0	5	10	0	0				**
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 28)	( 56)	( 0)	( 0)				
	squamous cell hyperplasia with atypia	0	0	0	0	0	0	0	0	0	0	0	0	2	1	0	0				
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 11)	( 6)	( 0)	( 0)				
	hyperplasia:nasal gland	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0				
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)				
	hyperplasia with atypia:transitional epithelium	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0				
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 11)	( 0)	( 0)	( 0)				

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

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 19

Organ	Findings	Group Name No. of Animals on Study				0 ppm				3 ppm				10 ppm				30 ppm			
		Grade				9				12				10				18			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																					
nasal cavit		< 9>				<12>				<10>				<18>							
	hyperplasia:transitional epithelium	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )
	atrophy:olfactory epithelium	0	0	0	0	0	0	0	0	0	0	0	0	8	1	0	0 *	8	1	0	0 *
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 44 )	( 6 )	( 0 )	( 0 )	( 44 )	( 6 )	( 0 )	( 0 )
	necrosis:olfactory epithelium	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )
	necrosis:respiratory epithelium	0	0	0	0	0	0	0	0	2	0	0	0	3	1	0	0	3	1	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 20 )	( 0 )	( 0 )	( 0 )	( 17 )	( 6 )	( 0 )	( 0 )	( 17 )	( 6 )	( 0 )	( 0 )
	thickening of bone:turbinate	0	0	0	0	0	0	0	0	2	0	0	0	6	7	0	0 **	6	7	0	0 **
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 20 )	( 0 )	( 0 )	( 0 )	( 33 )	( 39 )	( 0 )	( 0 )	( 33 )	( 39 )	( 0 )	( 0 )
larynx		< 9>				<12>				<10>				<18>							
	inflammation	0	0	0	0	0	0	0	0	2	1	0	0	5	0	0	0	5	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 20 )	( 10 )	( 0 )	( 0 )	( 28 )	( 0 )	( 0 )	( 0 )	( 28 )	( 0 )	( 0 )	( 0 )
lung		< 9>				<12>				<10>				<18>							
	congestion	0	4	0	0	0	7	0	0	0	2	0	0	0	0	0	0 *	0	0	0	0 *
		( 0 )	( 44 )	( 0 )	( 0 )	( 0 )	( 58 )	( 0 )	( 0 )	( 0 )	( 20 )	( 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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 20

Organ	Findings	Group Name No. of Animals on Study Grade				0 ppm 9				3 ppm 12				10 ppm 10				30 ppm 18			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																					
lung		< 9>				<12>				<10>				<18>							
	hemorrhage	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	( 11)	( 0)	( 0)	( 0)
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 11)	( 0)	( 0)	( 0)	( 11)	( 0)	( 0)	( 0)
	edema	0	1	0	0	0	2	0	0	0	0	0	0	0	0	0	0	( 0)	( 0)	( 0)	( 0)
		( 0)	( 11)	( 0)	( 0)	( 0)	( 17)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	inflammation	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	( 0)	( 0)	( 6)	( 0)
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)	( 6)	( 0)
	interstitial pneumonia	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	( 6)	( 0)	( 0)	( 0)
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)
{Hematopoietic system}																					
bone marrow		< 9>				<12>				<10>				<18>							
	granulation	1	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	( 0)	( 0)	( 0)	( 0)
		( 11)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	proliferation:histiocyte	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	( 0)	( 0)	( 6)	( 0)
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)	( 6)	( 0)
	increased hematopoiesis	1	0	0	0	0	1	0	0	0	0	0	0	1	2	0	0	( 6)	( 11)	( 0)	( 0)
		( 11)	( 0)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 6)	( 11)	( 0)	( 0)	( 6)	( 11)	( 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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 21

Organ	Findings	Group Name No. of Animals on Study Grade	0 ppm 9				3 ppm 12				10 ppm 10				30 ppm 18			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																		
bone marrow			< 9>				<12>				<10>				<18>			
	myelofibrosis		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)
	erythropoiesis:increased		1	0	0	0	1	1	0	0	1	0	0	0	2	3	0	0
			( 11)	( 0)	( 0)	( 0)	( 8)	( 8)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 11)	( 17)	( 0)	( 0)
	granulopoiesis:increased		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)	( 10)	( 0)	( 0)	( 0)	( 11)	( 0)	( 0)
spleen			< 9>				<12>				<10>				<18>			
	deposit of hemosiderin		5	0	0	0	8	0	0	0	6	1	0	0	7	0	0	0
			( 56)	( 0)	( 0)	( 0)	( 67)	( 0)	( 0)	( 0)	( 60)	( 10)	( 0)	( 0)	( 39)	( 0)	( 0)	( 0)
	extramedullary hematopoiesis		1	2	1	0	4	3	1	0	4	2	0	0	2	3	5	0
			( 11)	( 22)	( 11)	( 0)	( 33)	( 25)	( 8)	( 0)	( 40)	( 20)	( 0)	( 0)	( 11)	( 17)	( 28)	( 0)
{Circulatory system}																		
heart			< 9>				<12>				<10>				<18>			
	thrombus		0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 6)	( 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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 22

Organ	Findings	Group Name No. of Animals on Study Grade				0 ppm 9				3 ppm 12				10 ppm 10				30 ppm 18			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Circulatory system}																					
heart		< 9>				<12>				<10>				<18>							
	inflammatory cell nest	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	6	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )
	myocardial fibrosis	4	0	0	0	6	0	0	0	3	1	0	0	9	2	0	0	50	11	0	0
		( 44 )	( 0 )	( 0 )	( 0 )	( 50 )	( 0 )	( 0 )	( 0 )	( 30 )	( 10 )	( 0 )	( 0 )	( 50 )	( 11 )	( 0 )	( 0 )	( 50 )	( 11 )	( 0 )	( 0 )
artery/aort		< 9>				<12>				<10>				<18>							
	arteritis	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
{Digestive system}																					
stomach		< 9>				<12>				<10>				<18>							
	mineralization	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 20 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	inflammatory infiltration	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	erosion:forestomach	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	6	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0342  
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	Group Name No. of Animals on Study Grade	0 ppm 9				3 ppm 12				10 ppm 10				30 ppm 18			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
stomach			< 9>				<12>				<10>				<18>			
	ulcer:forestomach		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 )	( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	hyperplasia:forestomach		0	0	0	0	0	0	0	0	0	2	0	0	1	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 20 )	( 0 )	( 0 )	( 6 )	( 6 )	( 0 )	( 0 )
	erosion:glandular stomach		0	0	0	0	1	1	0	0	1	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 8 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )
small intes			< 9>				<12>				<10>				<18>			
	erosion		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 )
liver			< 9>				<12>				<10>				<18>			
	herniation		1	0	0	0	1	0	0	0	5	0	0	0	1	0	0	0
			( 11 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 50 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )
	peliosis-like lesion		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 )
	necrosis:central		0	1	0	0	0	0	0	0	0	0	0	0	3	0	0	0
			( 0 )	( 11 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 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. : 0342  
 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 No. of Animals on Study Grade				0 ppm 9				3 ppm 12				10 ppm 10				30 ppm 18			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																					
liver		< 9>				<12>				<10>				<18>							
	necrosis:focal	1 ( 11)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 17)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 11)	0 ( 0)	0 ( 0)	0 ( 0)				
	fatty change	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 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)				
	granulation	3 ( 33)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)				
	extramedullary hematopoiesis	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 11)	0 ( 0)	0 ( 0)	0 ( 0)				
	acidophilic cell focus	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)				
	basophilic cell focus	2 ( 22)	0 ( 0)	0 ( 0)	0 ( 0)	5 ( 42)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 40)	0 ( 0)	0 ( 0)	0 ( 0)	8 ( 44)	1 ( 6)	0 ( 0)	0 ( 0)				
	bile duct hyperplasia	3 ( 33)	0 ( 0)	0 ( 0)	0 ( 0)	5 ( 42)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 40)	0 ( 0)	0 ( 0)	0 ( 0)	7 ( 39)	0 ( 0)	0 ( 0)	0 ( 0)				
pancreas		< 9>				<12>				<10>				<18>							
	atrophy	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)				

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

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 25

Organ	Findings	Group Name No. of Animals on Study				0 ppm				3 ppm				10 ppm				30 ppm			
		Grade				9				12				10				18			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																					
kidney																					
	hyaline droplet	< 9>				<12>				<10>				<18>							
		8	0	0	0	11	0	0	0	7	0	0	0	16	0	0	0				
		( 89)	( 0)	( 0)	( 0)	( 92)	( 0)	( 0)	( 0)	( 70)	( 0)	( 0)	( 0)	( 89)	( 0)	( 0)	( 0)				
	inflammatory infiltration	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0				
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)				
	chronic nephropathy	2	0	0	0	3	0	1	0	4	0	1	0	9	2	0	0				
		( 22)	( 0)	( 0)	( 0)	( 25)	( 0)	( 8)	( 0)	( 40)	( 0)	( 10)	( 0)	( 50)	( 11)	( 0)	( 0)				
	hydronephrosis	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0				
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)				
	papillary necrosis	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0				
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)				
	mineralization:cortico-medullary junction	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0				
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 20)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)				
	mineralization:pelvis	2	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0				
		( 22)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)				
	mineralization:cortex	0	0	0	0	0	0	0	0	1	0	0	0	1	1	0	0				
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 6)	( 6)	( 0)	( 0)				

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

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

b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0342  
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 No. of Animals on Study Grade	0 ppm 9				3 ppm 12				10 ppm 10				30 ppm 18			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																		
kidney	atypical tubule hyperplasia		< 9>				<12>				<10>				<18>			
			0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)
urin bladd	simple hyperplasia:transitional epithelium		< 9>				<12>				<10>				<18>			
			0	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0
			( 0)	( 11)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)
{Endocrine system}																		
pituitary	angiectasis		< 9>				<12>				<10>				<18>			
			0	0	0	0	0	0	0	0	0	1	0	0	4	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 22)	( 0)	( 0)	( 0)
	cyst		1	1	0	0	3	0	0	0	3	2	0	0	4	9	0	0 *
			( 11)	( 11)	( 0)	( 0)	( 25)	( 0)	( 0)	( 0)	( 30)	( 20)	( 0)	( 0)	( 22)	( 50)	( 0)	( 0)
	hyperplasia		0	1	0	0	0	0	0	0	0	0	0	0	0	2	0	0
			( 0)	( 11)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 11)	( 0)	( 0)
	Rathke pouch		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 11)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

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. : 0342  
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	Group Name No. of Animals on Study				0 ppm 9				3 ppm 12				10 ppm 10				30 ppm 18			
		Grade				1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																					
pituitary		< 9>				<12>				<10>				<18>							
	focal hypertrophy	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 11)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
thyroid		< 9>				<12>				<10>				<18>							
	ultimibranhial body remanet	0	0	0	0	1	0	0	0	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)	( 0)	( 0)	( 0)
	C-cell hyperplasia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 17)	( 0)	( 0)	( 0)
	focal follicular cell hyperplasia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 6)	( 0)	( 0)	( 0)
adrenal		< 9>				<12>				<10>				<18>							
	hemorrhage	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 8)	( 8)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	peliosis-like lesion	2	1	1	0	4	3	0	0	1	1	0	0	6	1	0	0	6	1	0	0
		( 22)	( 11)	( 11)	( 0)	( 33)	( 25)	( 0)	( 0)	( 10)	( 10)	( 0)	( 0)	( 33)	( 6)	( 0)	( 0)	( 33)	( 6)	( 0)	( 0)
	hyperplasia:cortical cell	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 11)	( 0)	( 0)	( 0)	( 11)	( 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. : 0342  
ANIMAL : RAT F344/DuCrJ  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 28

Organ	Findings	Group Name No. of Animals on Study Grade	0 ppm 9				3 ppm 12				10 ppm 10				30 ppm 18			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																		
adrenal	hyperplasia:medulla		< 9>				<12>				<10>				<18>			
			0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )
	focal fatty change:cortex																	
			0	0	0	0	0	0	0	0	2	3	0	0 *	2	5	1	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 20 )	( 30 )	( 0 )	( 0 )	( 11 )	( 28 )	( 6 )	( 0 )
{Reproductive system}																		
ovary	cyst		< 9>				<12>				<10>				<18>			
			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 )
uterus	hemorrhage		< 9>				<12>				<10>				<18>			
			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 )	( 6 )	( 0 )
	cystic endometrial hyperplasia																	
			0	0	0	0	0	1	0	0	1	0	0	0	0	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )
mammary gl	galactoceles		< 9>				<12>				<10>				<18>			
			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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 29

		Group Name	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	9				12				10				18			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Nervous system}																		
brain																		
	hemorrhage		< 9>				<12>				<10>				<18>			
			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 )	( 6 )	( 0 )	( 0 )	( 0 )
	inflammatory infiltration		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )
	gliosis		0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )
{Special sense organs/appendage}																		
eye																		
	retinal atrophy		< 9>				<12>				<10>				<18>			
			3	0	0	0	4	0	0	0	7	0	0	0	14	0	0	0
			( 33 )	( 0 )	( 0 )	( 0 )	( 33 )	( 0 )	( 0 )	( 0 )	( 70 )	( 0 )	( 0 )	( 0 )	( 78 )	( 0 )	( 0 )	( 0 )
Harder gl																		
	degeneration		< 9>				<12>				<10>				<18>			
			1	0	0	0	1	0	0	0	1	1	0	0	2	0	0	0
			( 11 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 10 )	( 10 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )
nasolacr d																		
	inflammation		< 9>				<12>				<10>				<18>			
			3	2	0	0	4	2	0	0	3	0	0	0	2	0	0	0 *
			( 33 )	( 22 )	( 0 )	( 0 )	( 33 )	( 17 )	( 0 )	( 0 )	( 30 )	( 0 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 30

Organ	Findings	Group Name				0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study				9				12				10				18			
		Grade																			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4				
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)			

(Musculoskeletal system)

bone	osteosclerosis	< 9>				<12>				<10>				<18>			
		0	0	0	0	1	0	0	0	0	0	0	0	2	2	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 11 )	( 11 )	( 0 )	( 0 )
artculus	arthritis	< 9>				<12>				<10>				<18>			
		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 )	( 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 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 6

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : FEMALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 16

Organ	Findings	Group Name No. of Animals on Study Grade				0 ppm 41				3 ppm 38				10 ppm 39				30 ppm 32			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Integumentary system/appandage}																					
skin/app		<41>				<38>				<39>				<32>							
	hyperplasia:epidermis	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	scab	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)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
{Respiratory system}																					
nasal cavit		<41>				<38>				<39>				<32>							
	thrombus	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	mineralization	37	0	0	0	7	0	0	0 **	13	0	0	0 **	27	0	0	0	0	0	0	0
		( 90)	( 0)	( 0)	( 0)	( 18)	( 0)	( 0)	( 0)	( 33)	( 0)	( 0)	( 0)	( 84)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	squamous 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)	( 0)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)	( 0)	( 0)	( 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
		( 0)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	eosinophilic change:olfactory epithelium	6	26	9	0	0	10	28	0 **	1	20	18	0 *	3	27	2	0	0	0	0	0
		( 15)	( 63)	( 22)	( 0)	( 0)	( 26)	( 74)	( 0)	( 3)	( 51)	( 46)	( 0)	( 9)	( 84)	( 6)	( 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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 17

Organ	Findings	Group Name No. of Animals on Study Grade				0 ppm 41				3 ppm 38				10 ppm 39				30 ppm 32			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																					
nasal cavit		<41>				<38>				<39>				<32>							
	eosinophilic change:respiratory epithelium	31	6	0	0	32	2	0	0	32	1	0	0	21	2	0	0				
		( 76 )	( 15 )	( 0 )	( 0 )	( 84 )	( 5 )	( 0 )	( 0 )	( 82 )	( 3 )	( 0 )	( 0 )	( 66 )	( 6 )	( 0 )	( 0 )				
	inflammation:foreign body	4	0	0	0	3	0	0	0	1	0	0	0	1	0	0	0				
		( 10 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )				
	inflammation:respiratory epithelium	1	0	0	0	0	0	0	0	3	0	0	0	14	3	0	0 **				
		( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 44 )	( 9 )	( 0 )	( 0 )				
	inflammation: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 )	( 3 )	( 0 )	( 0 )	( 0 )				
	respiratory metaplasia:olfactory epithelium	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0				
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )				
	respiratory metaplasia:gland	41	0	0	0	37	0	0	0	39	0	0	0	31	0	0	0				
		(100)	( 0 )	( 0 )	( 0 )	( 97 )	( 0 )	( 0 )	( 0 )	(100)	( 0 )	( 0 )	( 0 )	( 97 )	( 0 )	( 0 )	( 0 )				
	inflammation:transitional epithelium	6	1	0	0	13	0	0	0	13	0	0	0	7	0	0	0				
		( 15 )	( 2 )	( 0 )	( 0 )	( 34 )	( 0 )	( 0 )	( 0 )	( 33 )	( 0 )	( 0 )	( 0 )	( 22 )	( 0 )	( 0 )	( 0 )				
	squamous cell metaplasia:respiratory epithelium	0	0	0	0	0	0	0	0	2	0	0	0	4	0	0	0				
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )				

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

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

b : 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. : 0342  
ANIMAL : RAT F344/DuCrJ  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 18

		Group Name No. of Animals on Study Grade				0 ppm 41				3 ppm 38				10 ppm 39				30 ppm 32			
Organ_____	Findings_____	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																					
nasal cavit		<41>				<38>				<39>				<32>							
	squamous cell metaplasia with atypia:respiratory epithelium	0	0	0	0	0	0	0	0	1	0	0	0	5	16	0	0	**			
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 16 )	( 50 )	( 0 )	( 0 )				
	squamous cell hyperplasia with atypia	0	0	0	0	0	0	0	0	0	0	0	0	6	1	0	0	**			
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 19 )	( 3 )	( 0 )	( 0 )				
	hyperplasia with atypia:nasal gland	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 )				
	hyperplasia with atypia:transitional epithelium	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0				
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )				
	hyperplasia:transitional epithelium	0	0	0	0	2	0	0	0	7	0	0	0 *	12	2	0	0	**			
		( 0 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 18 )	( 0 )	( 0 )	( 0 )	( 38 )	( 6 )	( 0 )	( 0 )				
	atrophy:olfactory epithelium	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 )	( 13 )	( 0 )	( 0 )	( 0 )				
	thickening of bone:turbinate	0	0	0	0	0	0	0	0	15	0	0	0 **	14	15	0	0	**			
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 38 )	( 0 )	( 0 )	( 0 )	( 44 )	( 47 )	( 0 )	( 0 )				
larynx		<41>				<38>				<39>				<32>							
	inflammation	13	0	0	0	11	0	0	0	13	1	0	0	8	0	0	0				
		( 32 )	( 0 )	( 0 )	( 0 )	( 29 )	( 0 )	( 0 )	( 0 )	( 33 )	( 3 )	( 0 )	( 0 )	( 25 )	( 0 )	( 0 )	( 0 )				

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

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrJ  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 19

Organ	Findings	Group Name No. of Animals on Study Grade	0 ppm 41				3 ppm 38				10 ppm 39				30 ppm 32			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
lung			<41>				<38>				<39>				<32>			
	foreign body granuloma		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 )
	accumulation of foamy cells		2	0	0	0	5	0	0	0	1	0	0	0	0	0	0	0
			( 5 )	( 0 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	bronchiolar-alveolar cell hyperplasia		0	0	0	0	0	0	0	0	2	1	0	0	1	2	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 5 )	( 3 )	( 0 )	( 0 )	( 3 )	( 6 )	( 0 )	( 0 )
{Hematopoietic system}																		
bone marrow			<41>				<38>				<39>				<32>			
	granulation		7	2	0	0	5	2	0	0	4	3	0	0	5	0	0	0
			( 17 )	( 5 )	( 0 )	( 0 )	( 13 )	( 5 )	( 0 )	( 0 )	( 10 )	( 8 )	( 0 )	( 0 )	( 16 )	( 0 )	( 0 )	( 0 )
	increased hematopoiesis		3	1	0	0	2	0	0	0	2	0	0	0	5	0	0	0
			( 7 )	( 2 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 16 )	( 0 )	( 0 )	( 0 )
	erythropoiesis:increased		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 )
thymus			<41>				<38>				<39>				<32>			
	cyst		2	0	0	0	3	0	0	0	0	0	0	0	2	0	0	0
			( 5 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )

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



STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 20

		Group Name No. of Animals on Study Grade				0 ppm 41				3 ppm 38				10 ppm 39				30 ppm 32			
Organ	Findings	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)				
{Hematopoietic system}																					
spleen		<41>				<38>				<39>				<32>							
	deposit of hemosiderin	35 ( 85)	0 ( 0)	0 ( 0)	0 ( 0)	33 ( 87)	0 ( 0)	0 ( 0)	0 ( 0)	35 ( 90)	0 ( 0)	0 ( 0)	0 ( 0)	21 ( 66)	0 ( 0)	0 ( 0)	0 ( 0)				
	fibrosis	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)				
	extramedullary hematopoiesis	29 ( 71)	7 ( 17)	0 ( 0)	0 ( 0)	30 ( 79)	4 ( 11)	0 ( 0)	0 ( 0)	33 ( 85)	4 ( 10)	0 ( 0)	0 ( 0)	22 ( 69)	4 ( 13)	1 ( 3)	0 ( 0)				
{Circulatory system}																					
heart		<41>				<38>				<39>				<32>							
	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)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)				
	mineralization	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)				
	inflammatory cell nest	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)				
	myocardial fibrosis	16 ( 39)	3 ( 7)	0 ( 0)	0 ( 0)	20 ( 53)	1 ( 3)	0 ( 0)	0 ( 0)	25 ( 64)	0 ( 0)	0 ( 0)	0 * ( 0)	17 ( 53)	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. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 21

		Group Name	0 ppm				3 ppm				10 ppm				30 ppm				
		No. of Animals on Study	41				38				39				32				
Organ_____	Findings_____	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	
{Digestive system}																			
tooth	inflammation		<41>				<38>				<39>				<32>				
		0	0	0	0	1	0	0	0	2	0	0	0	0	0	0	0	0	
			( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	
tongue	arteritis		<41>				<38>				<39>				<32>				
		0	0	0	0	5	0	0	0	4	0	0	0	1	0	0	0	0	
			( 0 )	( 0 )	( 0 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	
stomach	inflammatory infiltration		<41>				<38>				<39>				<32>				
		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 )	
	erosion:glandular stomach		1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )		
liver	hyperplasia:glandular stomach		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
					( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	herniation		<41>				<38>				<39>				<32>				
		14	0	0	0	3	0	0	0 *	9	0	0	0	3	0	0	0 *	0	0
			( 34 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 23 )	( 0 )	( 0 )	( 0 )	( 9 )	( 0 )	( 0 )	( 0 )	
	peliosis-like lesion		2	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0
					( 5 )	( 0 )	( 0 )	( 0 )	( 3 )	( 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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 22

		Group Name	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	41				38				39				32			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
liver			<41>				<38>				<39>				<32>			
	necrosis:focal		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 8)	1 ( 3)	0 ( 0)	0 ( 0)	3 ( 8)	1 ( 3)	0 ( 0)	0 ( 0)	4 ( 13)	1 ( 3)	0 ( 0)	0 ( 0)
	fatty change		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)
	inflammatory infiltration		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)
	lymphocytic infiltration		1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)	2 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	granulation		25 ( 61)	2 ( 5)	0 ( 0)	0 ( 0)	21 ( 55)	6 ( 16)	1 ( 3)	0 ( 0)	22 ( 56)	4 ( 10)	0 ( 0)	0 ( 0)	11 ( 34)	4 ( 13)	0 ( 0)	0 ( 0)
	organization		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)
	perivascular inflammation		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)
	fibrosis:focal		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)	

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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 23

		Group Name	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	41				38				39				32			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
liver																		
	extramedullary hematopoiesis		<41>				<38>				<39>				<32>			
			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 )
	clear cell focus		1	0	0	0	0	0	0	0	6	1	0	0	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 15 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	acidophilic cell focus		2	2	0	0	2	1	0	0	4	1	0	0	5	1	0	0
			( 5 )	( 5 )	( 0 )	( 0 )	( 5 )	( 3 )	( 0 )	( 0 )	( 10 )	( 3 )	( 0 )	( 0 )	( 16 )	( 3 )	( 0 )	( 0 )
	basophilic cell focus		32	3	0	0	24	9	0	0	29	4	0	0	22	3	0	0
			( 78 )	( 7 )	( 0 )	( 0 )	( 63 )	( 24 )	( 0 )	( 0 )	( 74 )	( 10 )	( 0 )	( 0 )	( 69 )	( 9 )	( 0 )	( 0 )
	bile duct hyperplasia		30	0	0	0	26	1	0	0	32	1	0	0	22	0	0	0
			( 73 )	( 0 )	( 0 )	( 0 )	( 68 )	( 3 )	( 0 )	( 0 )	( 82 )	( 3 )	( 0 )	( 0 )	( 69 )	( 0 )	( 0 )	( 0 )
	cholangiofibrosis		0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
pancreas																		
	atrophy		<41>				<38>				<39>				<32>			
			1	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )
	islet cell hyperplasia		0	1	0	0	1	1	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 2 )	( 0 )	( 0 )	( 3 )	( 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. : 0342  
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				0 ppm 41				3 ppm 38				10 ppm 39				30 ppm 32					
		Grade				1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4		
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	
{Urinary system}																							
kidney		<41>				<38>				<39>				<32>									
	infarct	0	0	0	0	2	0	0	0	1	0	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 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	
	cyst	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	
	hyaline droplet	40	0	0	0	37	0	0	0	39	0	0	0	32	0	0	0	0	0	0	0	0	
		( 98 )	( 0 )	( 0 )	( 0 )	( 97 )	( 0 )	( 0 )	( 0 )	( 100 )	( 0 )	( 0 )	( 0 )	( 100 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	
	chronic nephropathy	30	6	0	0	22	9	5	0 *	22	10	2	0	19	8	3	0						
		( 73 )	( 15 )	( 0 )	( 0 )	( 58 )	( 24 )	( 13 )	( 0 )	( 56 )	( 26 )	( 5 )	( 0 )	( 59 )	( 25 )	( 9 )	( 0 )						
	mineralization:cortico-medullary junction	1	0	0	0	2	0	0	0	1	0	0	0	0	0	0	0						
		( 2 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )						
	mineralization:papilla	2	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0						
		( 5 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )						
	mineralization:pelvis	7	0	0	0	2	0	0	0	0	0	0	0 *	2	0	0	0						
		( 17 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )						

{Endocrine system}

pituitary		<41>				<38>				<39>				<32>							
	angiectasis	3	2	0	0	7	2	1	0	0	5	1	0	1	1	0	0				
		( 7 )	( 5 )	( 0 )	( 0 )	( 18 )	( 5 )	( 3 )	( 0 )	( 0 )	( 13 )	( 3 )	( 0 )	( 3 )	( 3 )	( 0 )	( 0 )				

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

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

b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrJ  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 25

		Group Name	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	41				38				39				32			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																		
pituitary			<41>				<38>				<39>				<32>			
	cyst		12	7	2	0	16	7	2	0	15	7	0	0	16	4	2	0
			( 29)	( 17)	( 5)	( 0)	( 42)	( 18)	( 5)	( 0)	( 38)	( 18)	( 0)	( 0)	( 50)	( 13)	( 6)	( 0)
	hyperplasia		4	3	0	0	3	1	0	0	7	7	0	0	4	3	1	0
			( 10)	( 7)	( 0)	( 0)	( 8)	( 3)	( 0)	( 0)	( 18)	( 18)	( 0)	( 0)	( 13)	( 9)	( 3)	( 0)
	Rathke pouch		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)	( 6)	( 0)	( 0)	( 0)
	focal hypertrophy		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)	( 6)	( 0)	( 0)	( 0)
thyroid			<41>				<38>				<39>				<32>			
	ultimibranchial body remanet		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)
	C-cell hyperplasia		12	1	0	0	8	2	0	0	13	0	0	0	6	0	0	0
			( 29)	( 2)	( 0)	( 0)	( 21)	( 5)	( 0)	( 0)	( 33)	( 0)	( 0)	( 0)	( 19)	( 0)	( 0)	( 0)
	focal follicular cell hyperplasia		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 2)	( 0)	( 0)	( 0)	( 3)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
adrenal			<41>				<38>				<39>				<32>			
	hemorrhage		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 26

		Group Name No. of Animals on Study Grade				0 ppm 41				3 ppm 38				10 ppm 39				30 ppm 32			
Organ	Findings	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)				
{Endocrine system}																					
adrenal		<41>				<38>				<39>				<32>							
	peliosis-like lesion	21 ( 51)	18 ( 44)	0 ( 0)	0 ( 0)	24 ( 63)	8 ( 21)	0 ( 0)	0 ( 0)	28 ( 72)	6 ( 15)	0 ( 0)	0 *	21 ( 66)	5 ( 16)	0 ( 0)	0 *				
	cyst	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)				
	extramedullary hematopoiesis	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)				
	hyperplasia:cortical cell	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 5)	0 ( 0)	0 ( 0)	1 ( 3)	3 ( 9)	0 ( 0)	0 ( 0)				
	hyperplasia:medulla	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 5)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)				
	focal fatty change:cortex	8 ( 20)	2 ( 5)	0 ( 0)	0 ( 0)	12 ( 32)	1 ( 3)	0 ( 0)	0 ( 0)	9 ( 23)	3 ( 8)	0 ( 0)	0 ( 0)	8 ( 25)	5 ( 16)	0 ( 0)	0 ( 0)				
{Reproductive system}																					
ovary		<41>				<38>				<39>				<32>							
	cyst	1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 5)	0 ( 0)	0 ( 0)	1 ( 3)	2 ( 5)	0 ( 0)	0 ( 0)	2 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)				

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

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 27

		Group Name	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	41				38				39				32			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Reproductive system}																		
uterus			<41>				<38>				<39>				<32>			
	dilatation		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 )
	inflammation		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	hyperplasia:epithelium		1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	hyperplasia:gland		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 )
	cystic endometrial hyperplasia		6	2	0	0	3	1	0	0	2	0	0	0	2	3	0	0
			( 15 )	( 5 )	( 0 )	( 0 )	( 8 )	( 3 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 6 )	( 9 )	( 0 )	( 0 )
vagina			<41>				<38>				<39>				<32>			
	squamous 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 )
mammary gl			<41>				<38>				<39>				<32>			
	hyperplasia		1	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 28

		Group Name	0 ppm				3 ppm				10 ppm				30 ppm			
		No. of Animals on Study	41				38				39				32			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Reproductive system}																		
mammary gl			<41>				<38>				<39>				<32>			
	galactoceles		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )
{Nervous system}																		
brain			<41>				<38>				<39>				<32>			
	necrosis:focal		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 )
	inflammatory infiltration		0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )	( 0 )	( 3 )	( 0 )	( 0 )
	gliosis		0	0	0	0	2	0	0	0	0	0	0	0	0	2	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 5 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )
{Special sense organs/appendage}																		
eye			<41>				<38>				<39>				<32>			
	cataract		0	3	0	0	0	1	1	0	0	2	0	0	0	0	0	0
			( 0 )	( 7 )	( 0 )	( 0 )	( 0 )	( 3 )	( 3 )	( 0 )	( 0 )	( 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. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 29

Organ	Findings	Group Name No. of Animals on Study Grade				0 ppm 41				3 ppm 38				10 ppm 39				30 ppm 32			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Special sense organs/appendage}																					
eye		<41>				<38>				<39>				<32>							
	retinal atrophy	39 ( 95)	1 ( 2)	1 ( 2)	0 ( 0)	36 ( 95)	0 ( 0)	2 ( 5)	0 ( 0)	37 ( 95)	0 ( 0)	2 ( 5)	0 ( 0)	32 (100)	0 ( 0)	0 ( 0)	0 ( 0)				
	keratitis	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)				
	iritis	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)				
Harder gl		<41>				<38>				<39>				<32>							
	degeneration	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 6)	1 ( 3)	0 ( 0)	0 ( 0)				
	lymphocytic infiltration	3 ( 7)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	4 (10)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)				
	granulation	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)				
	hyperplasia:mast cell	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 3)	0 ( 0)	0 ( 0)	0 ( 0)				
nasolacr d		<41>				<38>				<39>				<32>							
	inflammation	19 ( 46)	4 (10)	0 ( 0)	0 ( 0)	9 ( 24)	4 (11)	0 ( 0)	0 ( 0)	5 (13)	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 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. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 30

Organ	Findings	Group Name No. of Animals on Study Grade	0 ppm 41				3 ppm 38				10 ppm 39				30 ppm 32			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

{Musculoskeletal system}

bone	osteosclerosis	<41>				<38>				<39>				<32>			
		3	1	1	0	5	0	0	0	2	1	0	0	7	0	0	0
		( 7 )	( 2 )	( 2 )	( 0 )	( 13 )	( 0 )	( 0 )	( 0 )	( 5 )	( 3 )	( 0 )	( 0 )	( 22 )	( 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 K 1

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

STUDY NO. : 0342  
 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	0 ppm	3 ppm	10 ppm	30 ppm
0 - 52	NO. OF EXAMINED ANIMALS		0	0	0	0
	NO. OF ANIMALS WITH TUMORS		0	0	0	0
	NO. OF ANIMALS WITH SINGLE TUMORS		0	0	0	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	0
	NO. OF BENIGN TUMORS		0	0	0	0
	NO. OF MALIGNANT TUMORS		0	0	0	0
	NO. OF TOTAL TUMORS		0	0	0	0
53 - 78	NO. OF EXAMINED ANIMALS		1	4	0	4
	NO. OF ANIMALS WITH TUMORS		1	3	0	4
	NO. OF ANIMALS WITH SINGLE TUMORS		1	2	0	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	1	0	4
	NO. OF BENIGN TUMORS		0	1	0	6
	NO. OF MALIGNANT TUMORS		1	3	0	4
	NO. OF TOTAL TUMORS		1	4	0	10
79 - 104	NO. OF EXAMINED ANIMALS		9	4	12	23
	NO. OF ANIMALS WITH TUMORS		9	4	12	22
	NO. OF ANIMALS WITH SINGLE TUMORS		3	0	3	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		6	4	9	22
	NO. OF BENIGN TUMORS		12	7	18	46
	NO. OF MALIGNANT TUMORS		6	2	13	29
	NO. OF TOTAL TUMORS		18	9	31	75
105 - 105	NO. OF EXAMINED ANIMALS		40	42	38	23
	NO. OF ANIMALS WITH TUMORS		39	40	38	23
	NO. OF ANIMALS WITH SINGLE TUMORS		11	10	10	1
	NO. OF ANIMALS WITH MULTIPLE TUMORS		28	30	28	22
	NO. OF BENIGN TUMORS		82	80	80	63
	NO. OF MALIGNANT TUMORS		13	7	14	27
	NO. OF TOTAL TUMORS		95	87	94	90

STUDY NO. : 0342  
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	0 ppm	3 ppm	10 ppm	30 ppm
0 - 105	NO. OF EXAMINED ANIMALS		50	50	50	50
	NO. OF ANIMALS WITH TUMORS		49	47	50	49
	NO. OF ANIMALS WITH SINGLE TUMORS		15	12	13	1
	NO. OF ANIMALS WITH MULTIPLE TUMORS		34	35	37	48
	NO. OF BENIGN TUMORS		94	88	98	115
	NO. OF MALIGNANT TUMORS		20	12	27	60
	NO. OF TOTAL TUMORS		114	100	125	175

(HPT070)

BAIS3

## APPENDIX K 2

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

STUDY NO. : 0342  
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	0 ppm	3 ppm	10 ppm	30 ppm
0 - 52	NO. OF EXAMINED ANIMALS		0	0	0	0
	NO. OF ANIMALS WITH TUMORS		0	0	0	0
	NO. OF ANIMALS WITH SINGLE TUMORS		0	0	0	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	0
	NO. OF BENIGN TUMORS		0	0	0	0
	NO. OF MALIGNANT TUMORS		0	0	0	0
	NO. OF TOTAL TUMORS		0	0	0	0
53 - 78	NO. OF EXAMINED ANIMALS		3	1	2	3
	NO. OF ANIMALS WITH TUMORS		2	0	2	2
	NO. OF ANIMALS WITH SINGLE TUMORS		2	0	2	1
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	1
	NO. OF BENIGN TUMORS		2	0	0	1
	NO. OF MALIGNANT TUMORS		0	0	2	2
	NO. OF TOTAL TUMORS		2	0	2	3
79 - 104	NO. OF EXAMINED ANIMALS		6	11	8	15
	NO. OF ANIMALS WITH TUMORS		5	11	8	15
	NO. OF ANIMALS WITH SINGLE TUMORS		3	8	2	3
	NO. OF ANIMALS WITH MULTIPLE TUMORS		2	3	6	12
	NO. OF BENIGN TUMORS		3	8	10	19
	NO. OF MALIGNANT TUMORS		4	6	9	13
	NO. OF TOTAL TUMORS		7	14	19	32
105 - 105	NO. OF EXAMINED ANIMALS		41	38	39	32
	NO. OF ANIMALS WITH TUMORS		26	29	31	28
	NO. OF ANIMALS WITH SINGLE TUMORS		12	16	9	6
	NO. OF ANIMALS WITH MULTIPLE TUMORS		14	13	22	22
	NO. OF BENIGN TUMORS		41	36	57	52
	NO. OF MALIGNANT TUMORS		6	10	7	13
	NO. OF TOTAL TUMORS		47	46	64	65



STUDY NO. : 0342  
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	0 ppm	3 ppm	10 ppm	30 ppm
0 - 105	NO. OF EXAMINED ANIMALS		50	50	49	50
	NO. OF ANIMALS WITH TUMORS		33	40	41	45
	NO. OF ANIMALS WITH SINGLE TUMORS		17	24	13	10
	NO. OF ANIMALS WITH MULTIPLE TUMORS		16	16	28	35
	NO. OF BENIGN TUMORS		46	44	67	72
	NO. OF MALIGNANT TUMORS		10	16	18	28
	NO. OF TOTAL TUMORS		56	60	85	100

(HPT070)

BAIS3

## APPENDIX L 1

HISTOLOGICAL FINDINGS : NEOPLASTIC LESIONS : SUMMARY

RAT : MALE

(2-YEAR STUDY)

STUDY NO. : 0342  
 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	0 ppm 50	3 ppm 50	10 ppm 50	30 ppm 50
{Integumentary system/appandage}						
skin/app	squamous cell papilloma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 3 ( 6%)
	trichoepithelioma		0 ( 0%)	1 ( 2%)	1 ( 2%)	1 ( 2%)
	keratoacanthoma		3 ( 6%)	3 ( 6%)	0 ( 0%)	2 ( 4%)
	sebaceous adenoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
subcutis	fibroma		<50> 10 ( 20%)	<50> 2 ( 4%)	<50> 10 ( 20%)	<50> 9 ( 18%)
	lipoma		0 ( 0%)	1 ( 2%)	1 ( 2%)	0 ( 0%)
	schwannoma		2 ( 4%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
	fibrosarcoma		0 ( 0%)	0 ( 0%)	1 ( 2%)	1 ( 2%)
	schwannoma:malignant		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
{Respiratory system}						
nasal cavit	adenoma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 3 ( 6%)	<50> 5 ( 10%)
	squamous cell carcinoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	14 ( 28%)
	adenocarcinoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)

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

STUDY NO. : 0342  
 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	0 ppm 50	3 ppm 50	10 ppm 50	30 ppm 50
{Respiratory system}						
nasal cavit	basal cell carcinoma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)
lung	bronchiolar-alveolar adenoma		<50> 2 ( 4%)	<50> 4 ( 8%)	<50> 5 ( 10%)	<50> 3 ( 6%)
	bronchiolar-alveolar carcinoma		4 ( 8%)	3 ( 6%)	2 ( 4%)	0 ( 0%)
{Hematopoietic system}						
lymph node	malignant lymphoma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)
spleen	histiocytic sarcoma		<50> 1 ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)
	mononuclear cell leukemia		8 ( 16%)	1 ( 2%)	4 ( 8%)	5 ( 10%)
{Digestive system}						
oral cavity	squamous cell carcinoma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)
salivary gl	fibroma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)
	adenocarcinoma		0 ( 0%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
stomach	squamous cell papilloma		<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)
small intes	adenocarcinoma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)

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

STUDY NO. : 0342  
 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	0 ppm 50	3 ppm 50	10 ppm 50	30 ppm 50
{Digestive system}						
small intes			<50>	<50>	<50>	<50>
	malignant fibrous histiocytoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
liver			<50>	<50>	<50>	<50>
	hepatocellular adenoma		0 ( 0%)	2 ( 4%)	1 ( 2%)	0 ( 0%)
	hepatocellular carcinoma		1 ( 2%)	0 ( 0%)	0 ( 0%)	0 ( 0%)
pancreas			<50>	<49>	<50>	<50>
	islet cell adenoma		4 ( 8%)	0 ( 0%)	1 ( 2%)	2 ( 4%)
	islet cell adenocarcinoma		2 ( 4%)	0 ( 0%)	0 ( 0%)	0 ( 0%)
{Urinary system}						
kidney			<50>	<50>	<50>	<50>
	renal cell adenoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
urin bladd			<50>	<50>	<50>	<50>
	transitional cell papilloma		1 ( 2%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
	transitional cell carcinoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
{Endocrine system}						
pituitary			<50>	<50>	<50>	<50>
	adenoma		11 ( 22%)	10 ( 20%)	9 ( 18%)	11 ( 22%)
	adenocarcinoma		0 ( 0%)	1 ( 2%)	0 ( 0%)	2 ( 4%)
thyroid			<50>	<50>	<50>	<50>
	C-cell adenoma		14 ( 28%)	17 ( 34%)	15 ( 30%)	14 ( 28%)
< a > a : Number of animals examined at the site b ( c ) b : Number of animals with neoplasm c : b / a * 100						

(HPT085)

BAIS3

STUDY NO. : 0342  
 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	0 ppm 50	3 ppm 50	10 ppm 50	30 ppm 50
{Endocrine system}						
thyroid	follicular adenoma		<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 2 ( 4%)	<50> 0 ( 0%)
	C-cell carcinoma		0 ( 0%)	0 ( 0%)	1 ( 2%)	1 ( 2%)
	follicular adenocarcinoma		0 ( 0%)	1 ( 2%)	0 ( 0%)	4 ( 8%)
adrenal	pheochromocytoma		<50> 5 ( 10%)	<50> 6 ( 12%)	<50> 4 ( 8%)	<50> 5 ( 10%)
	ganglioneuroma		0 ( 0%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
	pheochromocytoma:malignant		0 ( 0%)	0 ( 0%)	1 ( 2%)	1 ( 2%)
{Reproductive system}						
testis	interstitial cell tumor		<50> 41 ( 82%)	<50> 37 ( 74%)	<50> 44 ( 88%)	<50> 47 ( 94%)
	rete testis adenoma		1 ( 2%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
mammary gl	adenoma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)
	fibroadenoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	6 ( 12%)
prep/cli gl	adenoma		<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)
	adenocarcinoma		0 ( 0%)	1 ( 2%)	2 ( 4%)	0 ( 0%)

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

(HPT085)

BAIS3

STUDY NO. : 0342  
 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	0 ppm 50	3 ppm 50	10 ppm 50	30 ppm 50
{Nervous system}						
brain	malignant reticulosis		<50> 1 ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)
	glioma		0 ( 0%)	0 ( 0%)	0 ( 0%)	2 ( 4%)
{Special sense organs/appendage}						
Zymbal gl	squamous cell papilloma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)
	carcinoma		0 ( 0%)	1 ( 2%)	1 ( 2%)	1 ( 2%)
{Musculoskeletal system}						
muscle	sarcoma:NOS		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)
	chondroma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)
{Body cavities}						
peritoneum	mesothelioma		<50> 2 ( 4%)	<50> 3 ( 6%)	<50> 12 ( 24%)	<50> 22 ( 44%)
	schwannoma:malignant		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)
retroperit	sarcoma:NOS		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. : 0342  
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	0 ppm 50	3 ppm 50	10 ppm 49	30 ppm 50
{Integumentary system/appandage}						
skin/app			<50>	<50>	<49>	<50>
	squamous cell papilloma		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
	keratoacanthoma		0 ( 0%)	0 ( 0%)	1 ( 2%)	1 ( 2%)
	trichoepithelioma:malignant		1 ( 2%)	0 ( 0%)	0 ( 0%)	0 ( 0%)
subcutis			<50>	<50>	<49>	<50>
	fibroma		0 ( 0%)	0 ( 0%)	0 ( 0%)	2 ( 4%)
	schwannoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
{Respiratory system}						
nasal cavit			<50>	<50>	<49>	<50>
	adenoma		0 ( 0%)	0 ( 0%)	4 ( 8%)	8 ( 16%)
	squamous cell carcinoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	2 ( 4%)
	adenocarcinoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	2 ( 4%)
lung			<50>	<50>	<49>	<50>
	bronchiolar-alveolar adenoma		1 ( 2%)	1 ( 2%)	1 ( 2%)	2 ( 4%)
	bronchiolar-alveolar carcinoma		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
{Hematopoietic system}						
lymph node			<50>	<50>	<49>	<50>
	malignant lymphoma		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)

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

STUDY NO. : 0342  
 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	0 ppm 50	3 ppm 50	10 ppm 49	30 ppm 50
{Hematopoietic system}						
spleen	osteosarcoma		<50> 0 ( 0%)	<50> 0 ( 0%)	<49> 1 ( 2%)	<50> 0 ( 0%)
	mononuclear cell leukemia		3 ( 6%)	3 ( 6%)	1 ( 2%)	8 ( 16%)
{Digestive system}						
oral cavity	squamous cell papilloma		<50> 0 ( 0%)	<50> 0 ( 0%)	<49> 1 ( 2%)	<50> 0 ( 0%)
	tongue		<50> 0 ( 0%)	<50> 1 ( 2%)	<49> 1 ( 2%)	<50> 1 ( 2%)
stomach	squamous cell papilloma		<50> 1 ( 2%)	<50> 0 ( 0%)	<49> 0 ( 0%)	<50> 2 ( 4%)
	small intes		<50> 0 ( 0%)	<50> 0 ( 0%)	<49> 0 ( 0%)	<50> 1 ( 2%)
pancreas	adenocarcinoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
	malignant fibrous histiocyoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
pancreas	islet cell adenoma		<50> 1 ( 2%)	<50> 1 ( 2%)	<49> 0 ( 0%)	<50> 0 ( 0%)
	acinar cell adenocarcinoma		1 ( 2%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
{Urinary system}						
kidney	hemangiosarcoma		<50> 0 ( 0%)	<50> 1 ( 2%)	<49> 0 ( 0%)	<50> 0 ( 0%)
	nephroblastoma		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. : 0342  
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	0 ppm 50	3 ppm 50	10 ppm 49	30 ppm 50
{Urinary system}						
urin bladd	transitional cell papilloma		<50> 1 ( 2%)	<50> 1 ( 2%)	<49> 0 ( 0%)	<50> 0 ( 0%)
{Endocrine system}						
pituitary	adenoma		<50> 13 ( 26%)	<50> 12 ( 24%)	<49> 15 ( 31%)	<50> 10 ( 20%)
	adenocarcinoma		2 ( 4%)	4 ( 8%)	1 ( 2%)	1 ( 2%)
thyroid	C-cell adenoma		<50> 9 ( 18%)	<50> 5 ( 10%)	<49> 8 ( 16%)	<50> 7 ( 14%)
	follicular adenoma		0 ( 0%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
	C-cell carcinoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
adrenal	pheochromocytoma		<50> 3 ( 6%)	<50> 3 ( 6%)	<49> 1 ( 2%)	<50> 0 ( 0%)
	cortical adenoma		0 ( 0%)	0 ( 0%)	2 ( 4%)	0 ( 0%)
	sarcoma:NOS		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
	pheochromocytoma:malignant		0 ( 0%)	2 ( 4%)	0 ( 0%)	0 ( 0%)
{Reproductive system}						
ovary	hemangioma		<50> 0 ( 0%)	<50> 0 ( 0%)	<49> 0 ( 0%)	<50> 1 ( 2%)

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

STUDY NO. : 0342  
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	0 ppm 50	3 ppm 50	10 ppm 49	30 ppm 50
{Reproductive system}						
ovary	sertoli cell tumor		<50> 1 ( 2%)	<50> 0 ( 0%)	<49> 0 ( 0%)	<50> 0 ( 0%)
	granulosa-theca cell tumor		0 ( 0%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
uterus	endometrial stromal polyp		<50> 6 ( 12%)	<50> 11 ( 22%)	<49> 11 ( 22%)	<50> 13 ( 26%)
	adenocarcinoma		0 ( 0%)	0 ( 0%)	3 ( 6%)	0 ( 0%)
	hemangiosarcoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
	endometrial stromal sarcoma		1 ( 2%)	4 ( 8%)	4 ( 8%)	7 ( 14%)
vagina	hemangioma		<50> 0 ( 0%)	<50> 0 ( 0%)	<49> 0 ( 0%)	<50> 1 ( 2%)
	hemangiosarcoma		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
mammary gl	adenoma		<50> 2 ( 4%)	<50> 1 ( 2%)	<49> 3 ( 6%)	<50> 2 ( 4%)
	fibroadenoma		8 ( 16%)	6 ( 12%)	18 ( 37%)	17 ( 34%)
	adenocarcinoma		2 ( 4%)	1 ( 2%)	1 ( 2%)	2 ( 4%)
prep/cli gl	adenoma		<50> 0 ( 0%)	<50> 0 ( 0%)	<49> 0 ( 0%)	<50> 2 ( 4%)
{Nervous system}						
brain	glioma		<50> 0 ( 0%)	<50> 0 ( 0%)	<49> 0 ( 0%)	<50> 1 ( 2%)

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

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 10

Organ	Findings	Group Name No. of animals on Study	0 ppm 50	3 ppm 50	10 ppm 49	30 ppm 50
{Nervous system}						
brain	meningioma:malignant		<50> 0 ( 0%)	<50> 0 ( 0%)	<49> 1 ( 2%)	<50> 0 ( 0%)
{Special sense organs/appendage}						
Zymbal gl	carcinoma		<50> 0 ( 0%)	<50> 0 ( 0%)	<49> 1 ( 2%)	<50> 0 ( 0%)
{Musculoskeletal system}						
bone	osteoma		<50> 0 ( 0%)	<50> 0 ( 0%)	<49> 0 ( 0%)	<50> 1 ( 2%)
{Body cavities}						
peritoneum	fibroma		<50> 0 ( 0%)	<50> 0 ( 0%)	<49> 1 ( 2%)	<50> 0 ( 0%)
	mesothelioma		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
< a >      a : Number of animals examined at the site b ( c )      b : Number of animals with neoplasm      c : b / a * 100						
(HPT085)						

BAIS3

## APPENDIX M 1

### NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS, RAT : MALE (2-YEAR STUDY)

STUDY No. : 0342  
ANIMAL : RAT F344/DuCrj  
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 1

Group Name	0 ppm	3 ppm	10 ppm	30 ppm
SITE : skin/appendage TUMOR : squamous cell papilloma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	1/50( 2.0)	3/50( 6.0)
Adjusted rates(b)	0.0	0.0	2.63	8.70
Terminal rates(c)	0/40( 0.0)	0/42( 0.0)	1/38( 2.6)	2/23( 8.7)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0069**			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0138*			
Fisher Exact test(e)		P = N. C.	P = 0.5000	P = 0.1212
SITE : skin/appendage TUMOR : keratoacanthoma				
Tumor rate				
Overall rates(a)	3/50( 6.0)	3/50( 6.0)	0/50( 0.0)	2/50( 4.0)
Adjusted rates(b)	7.50	4.76	0.0	8.70
Terminal rates(c)	3/40( 7.5)	2/42( 4.8)	0/38( 0.0)	2/23( 8.7)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.5196			
Prevalence method(d)	P = 0.3621			
Combined analysis(d)	P = 0.4613			
Cochran-Armitage test(e)	P = 0.5998			
Fisher Exact test(e)		P = 0.6611	P = 0.1212	P = 0.5000
SITE : subcutis TUMOR : fibroma				
Tumor rate				
Overall rates(a)	10/50( 20.0)	2/50( 4.0)	10/50( 20.0)	9/50( 18.0)
Adjusted rates(b)	20.00	4.76	19.15	21.74
Terminal rates(c)	8/40( 20.0)	2/42( 4.8)	7/38( 18.4)	5/23( 21.7)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.8433			
Prevalence method(d)	P = 0.1043			
Combined analysis(d)	P = 0.1927			
Cochran-Armitage test(e)	P = 0.4750			
Fisher Exact test(e)		P = 0.0139*	P = 0.5984	P = 0.5000

STUDY No. : 0342  
ANIMAL : RAT F344/DuCrj  
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 2

Group Name	0 ppm	3 ppm	10 ppm	30 ppm
SITE : subcutis TUMOR : fibroma, fibrosarcoma				
Tumor rate				
Overall rates(a)	10/50( 20.0)	2/50( 4.0)	10/50( 20.0)	10/50( 20.0)
Adjusted rates(b)	20.00	4.76	19.15	23.08
Terminal rates(c)	8/40( 20.0)	2/42( 4.8)	7/38( 18.4)	5/23( 21.7)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.8433			
Prevalence method(d)	P = 0.0578			
Combined analysis(d)	P = 0.1201			
Cochran-Armitage test(e)	P = 0.3064			
Fisher Exact test(e)		P = 0.0139*	P = 0.5984	P = 0.5984
SITE : nasal cavity TUMOR : adenoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	3/50( 6.0)	5/50( 10.0)
Adjusted rates(b)	0.0	0.0	7.89	17.39
Terminal rates(c)	0/40( 0.0)	0/42( 0.0)	3/38( 7.9)	4/23( 17.4)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0006**			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0037**			
Fisher Exact test(e)		P = N. C.	P = 0.1212	P = 0.0281*
SITE : nasal cavity TUMOR : squamous cell carcinoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	0/50( 0.0)	14/50( 28.0)
Adjusted rates(b)	0.0	0.0	0.0	34.78
Terminal rates(c)	0/40( 0.0)	0/42( 0.0)	0/38( 0.0)	8/23( 34.8)
Statistical analysis				
Peto test				
Standard method(d)	P < 0.0001**?			
Prevalence method(d)	P < 0.0001**?			
Combined analysis(d)	P < 0.0001**?			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = N. C.	P = N. C.	P < 0.0001**



STUDY No. : 0342  
ANIMAL : RAT F344/DuCrj  
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 3

Group Name	0 ppm	3 ppm	10 ppm	30 ppm
SITE : nasal cavity TUMOR : adenoma, adenocarcinoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	3/50( 6.0)	6/50( 12.0)
Adjusted rates(b)	0.0	0.0	7.89	21.74
Terminal rates(c)	0/40( 0.0)	0/42( 0.0)	3/38( 7.9)	5/23( 21.7)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0001**			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0010**			
Fisher Exact test(e)		P = N. C.	P = 0.1212	P = 0.0133*
SITE : lung TUMOR : bronchiolar-alveolar adenoma				
Tumor rate				
Overall rates(a)	2/50( 4.0)	4/50( 8.0)	5/50( 10.0)	3/50( 6.0)
Adjusted rates(b)	4.76	8.33	13.16	10.34
Terminal rates(c)	1/40( 2.5)	3/42( 7.1)	5/38( 13.2)	2/23( 8.7)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.3220			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.9716			
Fisher Exact test(e)		P = 0.3389	P = 0.2180	P = 0.5000
SITE : lung TUMOR : bronchiolar-alveolar carcinoma				
Tumor rate				
Overall rates(a)	4/50( 8.0)	3/50( 6.0)	2/50( 4.0)	0/50( 0.0)
Adjusted rates(b)	10.00	4.76	2.63	0.0
Terminal rates(c)	4/40( 10.0)	2/42( 4.8)	1/38( 2.6)	0/23( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.5903			
Prevalence method(d)	P = 0.9683			
Combined analysis(d)	P = 0.9624			
Cochran-Armitage test(e)	P = 0.0481*			
Fisher Exact test(e)		P = 0.5000	P = 0.3389	P = 0.0587

STUDY No. : 0342  
ANIMAL : RAT F344/DuCrj  
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 4

Group Name	0 ppm	3 ppm	10 ppm	30 ppm
SITE : lung TUMOR : bronchiolar-alveolar adenoma, bronchiolar-alveolar carcinoma				
Tumor rate				
Overall rates(a)	6/50( 12.0)	7/50( 14.0)	7/50( 14.0)	3/50( 6.0)
Adjusted rates(b)	14.29	12.77	15.79	10.34
Terminal rates(c)	5/40( 12.5)	5/42( 11.9)	6/38( 15.8)	2/23( 8.7)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.5903			
Prevalence method(d)	P = 0.7406			
Combined analysis(d)	P = 0.7756			
Cochran-Armitage test(e)	P = 0.2091			
Fisher Exact test(e)		P = 0.5000	P = 0.5000	P = 0.2435
SITE : spleen TUMOR : mononuclear cell leukemia				
Tumor rate				
Overall rates(a)	8/50( 16.0)	1/50( 2.0)	4/50( 8.0)	5/50( 10.0)
Adjusted rates(b)	7.50	0.0	5.13	13.04
Terminal rates(c)	3/40( 7.5)	0/42( 0.0)	1/38( 2.6)	3/23( 13.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.6506			
Prevalence method(d)	P = 0.0828			
Combined analysis(d)	P = 0.2751			
Cochran-Armitage test(e)	P = 0.9916			
Fisher Exact test(e)		P = 0.0154*	P = 0.1783	P = 0.2768
SITE : pancreas TUMOR : islet cell adenoma				
Tumor rate				
Overall rates(a)	4/50( 8.0)	0/49( 0.0)	1/50( 2.0)	2/50( 4.0)
Adjusted rates(b)	10.00	0.0	2.63	8.70
Terminal rates(c)	4/40( 10.0)	0/41( 0.0)	1/38( 2.6)	2/23( 8.7)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.3158			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.8560			
Fisher Exact test(e)		P = 0.0612	P = 0.1811	P = 0.3389

STUDY No. : 0342  
ANIMAL : RAT F344/DuCrj  
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 5

Group Name	0 ppm	3 ppm	10 ppm	30 ppm
SITE : pancreas TUMOR : islet cell adenoma, islet cell adenocarcinoma				
Tumor rate				
Overall rates(a)	6/50( 12.0)	0/49( 0.0)	1/50( 2.0)	2/50( 4.0)
Adjusted rates(b)	15.00	0.0	2.63	8.70
Terminal rates(c)	6/40( 15.0)	0/41( 0.0)	1/38( 2.6)	2/23( 8.7)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.5440			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.4297			
Fisher Exact test(e)		P = 0.0142*	P = 0.0559	P = 0.1343
SITE : pituitary gland TUMOR : adenoma				
Tumor rate				
Overall rates(a)	11/50( 22.0)	10/50( 20.0)	9/50( 18.0)	11/50( 22.0)
Adjusted rates(b)	22.50	23.81	21.95	26.92
Terminal rates(c)	9/40( 22.5)	10/42( 23.8)	7/38( 18.4)	6/23( 26.1)
Statistical analysis				
Peto test				
Standard method(d)	P = 1.0000 ?			
Prevalence method(d)	P = 0.2050			
Combined analysis(d)	P = 0.2562			
Cochran-Armitage test(e)	P = 0.8898			
Fisher Exact test(e)		P = 0.5000	P = 0.4016	P = 0.5952
SITE : pituitary gland TUMOR : adenoma, adenocarcinoma				
Tumor rate				
Overall rates(a)	11/50( 22.0)	11/50( 22.0)	9/50( 18.0)	13/50( 26.0)
Adjusted rates(b)	22.50	26.19	21.95	30.77
Terminal rates(c)	9/40( 22.5)	11/42( 26.2)	7/38( 18.4)	7/23( 30.4)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.2496			
Prevalence method(d)	P = 0.1421			
Combined analysis(d)	P = 0.1161			
Cochran-Armitage test(e)	P = 0.5592			
Fisher Exact test(e)		P = 0.5952	P = 0.4016	P = 0.4076

STUDY No. : 0342  
ANIMAL : RAT F344/DuCrj  
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 6

Group Name	0 ppm	3 ppm	10 ppm	30 ppm
SITE : thyroid TUMOR : C-cell adenoma				
Tumor rate				
Overall rates(a)	14/50( 28.0)	17/50( 34.0)	15/50( 30.0)	14/50( 28.0)
Adjusted rates(b)	34.15	38.64	33.33	35.90
Terminal rates(c)	13/40( 32.5)	15/42( 35.7)	12/38( 31.6)	7/23( 30.4)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.4036			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.7514			
Fisher Exact test(e)		P = 0.3329	P = 0.5000	P = 0.5880
SITE : thyroid TUMOR : follicular adenocarcinoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	1/50( 2.0)	0/50( 0.0)	4/50( 8.0)
Adjusted rates(b)	0.0	2.38	0.0	14.29
Terminal rates(c)	0/40( 0.0)	1/42( 2.4)	0/38( 0.0)	3/23( 13.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0014**			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0073**			
Fisher Exact test(e)		P = 0.5000	P = N. C.	P = 0.0587
SITE : thyroid TUMOR : C-cell adenoma, C-cell carcinoma				
Tumor rate				
Overall rates(a)	14/50( 28.0)	17/50( 34.0)	16/50( 32.0)	15/50( 30.0)
Adjusted rates(b)	34.15	38.64	35.90	38.46
Terminal rates(c)	13/40( 32.5)	15/42( 35.7)	13/38( 34.2)	8/23( 34.8)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.3029			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.9427			
Fisher Exact test(e)		P = 0.3329	P = 0.4138	P = 0.5000

STUDY No. : 0342  
ANIMAL : RAT F344/DuCrj  
SEX : MALE

NEOPLASTIC LESIONS--INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 7

Group Name	0 ppm	3 ppm	10 ppm	30 ppm
SITE : thyroid TUMOR : follicular adenoma, follicular adenocarcinoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	2/50( 4.0)	2/50( 4.0)	4/50( 8.0)
Adjusted rates(b)	0.0	4.76	5.26	14.29
Terminal rates(c)	0/40( 0.0)	2/42( 4.8)	2/38( 5.3)	3/23( 13.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0114*			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0640			
Fisher Exact test(e)		P = 0.2475	P = 0.2475	P = 0.0587
SITE : adrenal gland TUMOR : pheochromocytoma				
Tumor rate				
Overall rates(a)	5/50( 10.0)	6/50( 12.0)	4/50( 8.0)	5/50( 10.0)
Adjusted rates(b)	12.50	14.29	8.33	14.29
Terminal rates(c)	5/40( 12.5)	6/42( 14.3)	3/38( 7.9)	3/23( 13.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.3886			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.8878			
Fisher Exact test(e)		P = 0.5000	P = 0.5000	P = 0.6297
SITE : adrenal gland TUMOR : pheochromocytoma, pheochromocytoma:malignant				
Tumor rate				
Overall rates(a)	5/50( 10.0)	6/50( 12.0)	5/50( 10.0)	6/50( 12.0)
Adjusted rates(b)	12.50	14.29	8.51	17.86
Terminal rates(c)	5/40( 12.5)	6/42( 14.3)	3/38( 7.9)	3/23( 13.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.3394			
Prevalence method(d)	P = 0.2496			
Combined analysis(d)	P = 0.2543			
Cochran-Armitage test(e)	P = 0.8241			
Fisher Exact test(e)		P = 0.5000	P = 0.6297	P = 0.5000

STUDY No. : 0342  
ANIMAL : RAT F344/DuCrj  
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 8

Group Name	0 ppm	3 ppm	10 ppm	30 ppm
SITE : testis TUMOR : interstitial cell tumor				
Tumor rate				
Overall rates(a)	41/50( 82.0)	37/50( 74.0)	44/50( 88.0)	47/50( 94.0)
Adjusted rates(b)	90.91	80.95	97.44	97.30
Terminal rates(c)	36/40( 90.0)	34/42( 81.0)	37/38( 97.4)	22/23( 95.7)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0001**			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0159*			
Fisher Exact test(e)		P = 0.2348	P = 0.2883	P = 0.0606
SITE : mammary gland TUMOR : fibroadenoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	0/50( 0.0)	6/50( 12.0)
Adjusted rates(b)	0.0	0.0	0.0	16.67
Terminal rates(c)	0/40( 0.0)	0/42( 0.0)	0/38( 0.0)	3/23( 13.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0805			
Prevalence method(d)	P < 0.0001**?			
Combined analysis(d)	P < 0.0001**?			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = N. C.	P = N. C.	P = 0.0133*
SITE : mammary gland TUMOR : adenoma, fibroadenoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	0/50( 0.0)	7/50( 14.0)
Adjusted rates(b)	0.0	0.0	0.0	20.00
Terminal rates(c)	0/40( 0.0)	0/42( 0.0)	0/38( 0.0)	4/23( 17.4)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0805			
Prevalence method(d)	P < 0.0001**?			
Combined analysis(d)	P < 0.0001**?			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = N. C.	P = N. C.	P = 0.0062**

STUDY No. : 0342  
ANIMAL : RAT F344/DuCrj  
SEX : MALE

# NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 9

Group Name	0 ppm	3 ppm	10 ppm	30 ppm
SITE : peritoneum TUMOR : mesothelioma				
Tumor rate				
Overall rates(a)	2/50( 4.0)	3/50( 6.0)	12/50( 24.0)	22/50( 44.0)
Adjusted rates(b)	5.00	4.76	25.00	32.00
Terminal rates(c)	2/40( 5.0)	2/42( 4.8)	9/38( 23.7)	7/23( 30.4)
Statistical analysis				
Peto test				
Standard method(d)	P < 0.0001**			
Prevalence method(d)	P = 0.0003**			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.5000	P = 0.0038**	P < 0.0001**

(HPT360A)

BAIS3

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

## APPENDIX M 2

### NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS, RAT : FEMALE (2-YEAR STUDY)



STUDY No. : 0342  
ANIMAL : RAT F344/DuCrj  
SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 10

Group Name	0 ppm	3 ppm	10 ppm	30 ppm
SITE : nasal cavity TUMOR : adenoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	4/49( 8.2)	8/50( 16.0)
Adjusted rates(b)	0.0	0.0	9.52	21.21
Terminal rates(c)	0/41( 0.0)	0/38( 0.0)	3/39( 7.7)	6/32( 18.8)
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 = N. C.	P = 0.0563	P = 0.0029**
SITE : nasal cavity TUMOR : adenoma, adenocarcinoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	4/49( 8.2)	10/50( 20.0)
Adjusted rates(b)	0.0	0.0	9.52	21.43
Terminal rates(c)	0/41( 0.0)	0/38( 0.0)	3/39( 7.7)	6/32( 18.8)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.1407			
Prevalence method(d)	P < 0.0001**			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = N. C.	P = 0.0563	P = 0.0006**
SITE : spleen TUMOR : mononuclear cell leukemia				
Tumor rate				
Overall rates(a)	3/50( 6.0)	3/50( 6.0)	1/49( 2.0)	8/50( 16.0)
Adjusted rates(b)	4.88	2.63	0.0	12.50
Terminal rates(c)	2/41( 4.9)	1/38( 2.6)	0/39( 0.0)	4/32( 12.5)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0599			
Prevalence method(d)	P = 0.0398*			
Combined analysis(d)	P = 0.0097**			
Cochran-Armitage test(e)	P = 0.0252*			
Fisher Exact test(e)		P = 0.6611	P = 0.3163	P = 0.0999

STUDY No. : 0342  
ANIMAL : RAT F344/DuCrj  
SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 11

Group Name	0 ppm	3 ppm	10 ppm	30 ppm
SITE : pituitary gland TUMOR : adenoma				
Tumor rate				
Overall rates(a)	13/50( 26.0)	12/50( 24.0)	15/49( 30.6)	10/50( 20.0)
Adjusted rates(b)	26.83	23.68	33.33	21.88
Terminal rates(c)	11/41( 26.8)	9/38( 23.7)	13/39( 33.3)	7/32( 21.9)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.7714			
Prevalence method(d)	P = 0.5165			
Combined analysis(d)	P = 0.6454			
Cochran-Armitage test(e)	P = 0.4711			
Fisher Exact test(e)		P = 0.5000	P = 0.3874	P = 0.3176
SITE : pituitary gland TUMOR : adenocarcinoma				
Tumor rate				
Overall rates(a)	2/50( 4.0)	4/50( 8.0)	1/49( 2.0)	1/50( 2.0)
Adjusted rates(b)	2.44	7.89	2.56	3.13
Terminal rates(c)	1/41( 2.4)	3/38( 7.9)	1/39( 2.6)	1/32( 3.1)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.8699			
Prevalence method(d)	P = 0.6075			
Combined analysis(d)	P = 0.7980			
Cochran-Armitage test(e)	P = 0.2947			
Fisher Exact test(e)		P = 0.3389	P = 0.5077	P = 0.5000
SITE : pituitary gland TUMOR : adenoma, adenocarcinoma				
Tumor rate				
Overall rates(a)	15/50( 30.0)	16/50( 32.0)	16/49( 32.7)	11/50( 22.0)
Adjusted rates(b)	29.27	31.58	35.90	25.00
Terminal rates(c)	12/41( 29.3)	12/38( 31.6)	14/39( 35.9)	8/32( 25.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.8905			
Prevalence method(d)	P = 0.5960			
Combined analysis(d)	P = 0.7811			
Cochran-Armitage test(e)	P = 0.2539			
Fisher Exact test(e)		P = 0.5000	P = 0.4729	P = 0.2472

STUDY No. : 0342  
ANIMAL : RAT F344/DuCrj  
SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 12

Group Name	0 ppm	3 ppm	10 ppm	30 ppm
SITE : thyroid TUMOR : C-cell adenoma				
Tumor rate				
Overall rates(a)	9/50( 18.0)	5/50( 10.0)	8/49( 16.3)	7/50( 14.0)
Adjusted rates(b)	21.95	11.36	20.00	16.67
Terminal rates(c)	9/41( 22.0)	4/38( 10.5)	7/39( 17.9)	5/32( 15.6)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.4560			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.9064			
Fisher Exact test(e)		P = 0.1940	P = 0.5184	P = 0.3929
SITE : thyroid TUMOR : C-cell adenoma, C-cell carcinoma				
Tumor rate				
Overall rates(a)	9/50( 18.0)	5/50( 10.0)	8/49( 16.3)	8/50( 16.0)
Adjusted rates(b)	21.95	11.36	20.00	19.44
Terminal rates(c)	9/41( 22.0)	4/38( 10.5)	7/39( 17.9)	6/32( 18.8)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.3250			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.8342			
Fisher Exact test(e)		P = 0.1940	P = 0.5184	P = 0.5000
SITE : adrenal gland TUMOR : pheochromocytoma				
Tumor rate				
Overall rates(a)	3/50( 6.0)	3/50( 6.0)	1/49( 2.0)	0/50( 0.0)
Adjusted rates(b)	7.32	7.89	2.56	0.0
Terminal rates(c)	3/41( 7.3)	3/38( 7.9)	1/39( 2.6)	0/32( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.9717			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0647			
Fisher Exact test(e)		P = 0.6611	P = 0.3163	P = 0.1212

STUDY No. : 0342  
ANIMAL : RAT F344/DuCrj  
SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 13

Group Name	0 ppm	3 ppm	10 ppm	30 ppm
SITE : adrenal gland TUMOR : pheochromocytoma, pheochromocytoma:malignant				
Tumor rate				
Overall rates(a)	3/50( 6.0)	5/50( 10.0)	1/49( 2.0)	0/50( 0.0)
Adjusted rates(b)	7.32	10.53	2.56	0.0
Terminal rates(c)	3/41( 7.3)	4/38( 10.5)	1/39( 2.6)	0/32( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.5280			
Prevalence method(d)	P = 0.9796			
Combined analysis(d)	P = 0.9855			
Cochran-Armitage test(e)	P = 0.0367*			
Fisher Exact test(e)		P = 0.3575	P = 0.3163	P = 0.1212
SITE : uterus TUMOR : endometrial stromal polyp				
Tumor rate				
Overall rates(a)	6/50( 12.0)	11/50( 22.0)	11/49( 22.4)	13/50( 26.0)
Adjusted rates(b)	14.63	26.19	26.83	34.29
Terminal rates(c)	6/41( 14.6)	9/38( 23.7)	9/39( 23.1)	10/32( 31.3)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0471*			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.1685			
Fisher Exact test(e)		P = 0.1434	P = 0.1330	P = 0.0624
SITE : uterus TUMOR : adenocarcinoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	3/49( 6.1)	0/50( 0.0)
Adjusted rates(b)	0.0	0.0	5.13	0.0
Terminal rates(c)	0/41( 0.0)	0/38( 0.0)	2/39( 5.1)	0/32( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.3409			
Prevalence method(d)	P = 0.4191			
Combined analysis(d)	P = 0.4388			
Cochran-Armitage test(e)	P = 0.9106			
Fisher Exact test(e)		P = N. C.	P = 0.1175	P = N. C.

STUDY No. : 0342  
 ANIMAL : RAT F344/DuCrj  
 SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 14

Group Name	0 ppm	3 ppm	10 ppm	30 ppm
SITE : uterus TUMOR : endometrial stromal sarcoma				
Tumor rate				
Overall rates(a)	1/50( 2.0)	4/50( 8.0)	4/49( 8.2)	7/50( 14.0)
Adjusted rates(b)	0.0	5.26	2.56	3.13
Terminal rates(c)	0/41( 0.0)	2/38( 5.3)	1/39( 2.6)	1/32( 3.1)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0152*			
Prevalence method(d)	P = 0.3505			
Combined analysis(d)	P = 0.0201*			
Cochran-Armitage test(e)	P = 0.0454*			
Fisher Exact test(e)		P = 0.1811	P = 0.1748	P = 0.0297*
SITE : mammary gland TUMOR : adenoma				
Tumor rate				
Overall rates(a)	2/50( 4.0)	1/50( 2.0)	3/49( 6.1)	2/50( 4.0)
Adjusted rates(b)	4.26	2.56	7.14	6.25
Terminal rates(c)	1/41( 2.4)	0/38( 0.0)	2/39( 5.1)	2/32( 6.3)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.3835			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.8301			
Fisher Exact test(e)		P = 0.5000	P = 0.4903	P = 0.6913
SITE : mammary gland TUMOR : fibroadenoma				
Tumor rate				
Overall rates(a)	8/50( 16.0)	6/50( 12.0)	18/49( 36.7)	17/50( 34.0)
Adjusted rates(b)	19.51	15.79	38.46	43.75
Terminal rates(c)	8/41( 19.5)	6/38( 15.8)	15/39( 38.5)	14/32( 43.8)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0014**			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0110*			
Fisher Exact test(e)		P = 0.3871	P = 0.0167*	P = 0.0317*

STUDY No. : 0342  
ANIMAL : RAT F344/DuCrj.  
SEX : FEMALE

# NEOPLASTIC LESIONS--INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 15

Group Name	0 ppm	3 ppm	10 ppm	30 ppm
SITE : mammary gland TUMOR : adenoma, fibroadenoma				
Tumor rate				
Overall rates(a)	10/50( 20.0)	7/50( 14.0)	20/49( 40.8)	17/50( 34.0)
Adjusted rates(b)	21.95	17.95	42.55	43.75
Terminal rates(c)	9/41( 22.0)	6/38( 15.8)	16/39( 41.0)	14/32( 43.8)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0112*			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0409*			
Fisher Exact test(e)		P = 0.2977	P = 0.0205*	P = 0.0880
SITE : mammary gland TUMOR : adenoma, fibroadenoma, adenocarcinoma				
Tumor rate				
Overall rates(a)	10/50( 20.0)	8/50( 16.0)	21/49( 42.9)	19/50( 38.0)
Adjusted rates(b)	21.95	20.51	44.68	46.88
Terminal rates(c)	9/41( 22.0)	7/38( 18.4)	17/39( 43.6)	15/32( 46.9)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.1346			
Prevalence method(d)	P = 0.0073**			
Combined analysis(d)	P = 0.0038**			
Cochran-Armitage test(e)	P = 0.0164*			
Fisher Exact test(e)		P = 0.3976	P = 0.0123*	P = 0.0385*

(HPT360A)

BAIS3

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

## APPENDIX N 1

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR : SUMMARY

RAT : MALE : ALL ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name No. of Animals on Study	0 ppm 50	3 ppm 50	10 ppm 50	30 ppm 50
{Respiratory system}						
nasal cavit			<50>	<50>	<50>	<50>
	leukemic cell infiltration		1	0	0	0
lung			<50>	<50>	<50>	<50>
	leukemic cell infiltration		6	1	3	2
	metastasis:thyroid tumor		0	0	0	1
	metastasis:peritoneum tumor		0	0	0	1
{Hematopoietic system}						
bone marrow			<50>	<50>	<50>	<50>
	leukemic cell infiltration		5	0	2	0
lymph node			<50>	<50>	<50>	<50>
	leukemic cell infiltration		3	0	0	0
	metastasis:peritoneum tumor		0	0	0	1
{Circulatory system}						
heart			<50>	<50>	<50>	<50>
	leukemic cell infiltration		2	0	0	0
{Digestive system}						
tongue			<50>	<50>	<50>	<50>
	leukemic cell infiltration		0	0	1	0
salivary gl			<50>	<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. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 2

Organ	Findings	Group Name No. of Animals on Study	0 ppm 50	3 ppm 50	10 ppm 50	30 ppm 50
{Digestive system}						
salivary gl	metastasis:subcutis tumor		<50> 0	<50> 0	<50> 1	<50> 1
stomach	leukemic cell infiltration		<50> 2	<50> 0	<50> 0	<50> 0
	metastasis:peritoneum tumor		0	0	0	1
small intes	leukemic cell infiltration		<50> 1	<50> 0	<50> 0	<50> 0
large intes	leukemic cell infiltration		<50> 1	<50> 0	<50> 0	<50> 0
	metastasis:peritoneum tumor		0	0	0	1
liver	leukemic cell infiltration		<50> 7	<50> 1	<50> 3	<50> 4
pancreas	leukemic cell infiltration		<50> 3	<49> 0	<50> 1	<50> 0
	metastasis:peritoneum tumor		0	0	0	1
{Urinary system}						
kidney	leukemic cell infiltration		<50> 1	<50> 1	<50> 0	<50> 1
urin bladd	leukemic cell infiltration		<50> 2	<50> 0	<50> 0	<50> 0
{Endocrine system}						
adrenal	leukemic cell infiltration		<50> 1	<50> 0	<50> 0	<50> 0
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 3

		Group Name	0 ppm	3 ppm	10 ppm	30 ppm
		No. of Animals on Study	50	50	50	50
Organ	Findings					
{Reproductive system}						
prostate	leukemic cell infiltration		<50> 2	<50> 0	<50> 0	<50> 0
{Nervous system}						
brain	leukemic cell infiltration		<50> 3	<50> 1	<50> 2	<50> 1
	metastasis:pituitary tumor		0	1	0	2
spinal cord	leukemic cell infiltration		<50> 2	<50> 1	<50> 1	<50> 0
{Body cavities}						
pleura	metastasis:peritoneum tumor		<50> 0	<50> 0	<50> 0	<50> 2
	metastasis:retroperitoneum tumor		0	0	0	1
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					

(JPT150)

BAIS3

## APPENDIX N 2

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR : SUMMARY

RAT : MALE : DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0342  
 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 No. of Animals on Study		0 ppm 10	3 ppm 8	10 ppm 12	30 ppm 27
Organ	Findings				
{Respiratory system}					
nasal cavit	leukemic cell infiltration	<10> 1	< 8> 0	<12> 0	<27> 0
lung	leukemic cell infiltration	<10> 5	< 8> 1	<12> 3	<27> 2
	metastasis:peritoneum tumor	0	0	0	1
{Hematopoietic system}					
bone marrow	leukemic cell infiltration	<10> 5	< 8> 0	<12> 2	<27> 0
lymph node	leukemic cell infiltration	<10> 3	< 8> 0	<12> 0	<27> 0
	metastasis:peritoneum tumor	0	0	0	1
{Circulatory system}					
heart	leukemic cell infiltration	<10> 2	< 8> 0	<12> 0	<27> 0
{Digestive system}					
tongue	leukemic cell infiltration	<10> 0	< 8> 0	<12> 1	<27> 0
salivary gl	leukemic cell infiltration	<10> 0	< 8> 0	<12> 1	<27> 0
	metastasis:subcutis tumor	0	0	0	1
< a >	a : Number of animals examined at the site				
b	b : Number of animals with lesion				

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 2

		Group Name	0 ppm	3 ppm	10 ppm	30 ppm
		No. of Animals on Study	10	8	12	27
Organ	Findings					
{Digestive system}						
stomach	leukemic cell infiltration		<10> 2	< 8> 0	<12> 0	<27> 0
	metastasis:peritoneum tumor		0	0	0	1
small intes	leukemic cell infiltration		<10> 1	< 8> 0	<12> 0	<27> 0
	leukemic cell infiltration		<10> 1	< 8> 0	<12> 0	<27> 0
large intes	leukemic cell infiltration		<10> 1	< 8> 0	<12> 0	<27> 0
	metastasis:peritoneum tumor		0	0	0	1
liver	leukemic cell infiltration		<10> 5	< 8> 1	<12> 3	<27> 2
	leukemic cell infiltration		<10> 3	< 8> 0	<12> 1	<27> 0
pancreas	leukemic cell infiltration		<10> 3	< 8> 0	<12> 1	<27> 0
	metastasis:peritoneum tumor		0	0	0	1
{Urinary system}						
kidney	leukemic cell infiltration		<10> 1	< 8> 1	<12> 0	<27> 0
	leukemic cell infiltration		<10> 2	< 8> 0	<12> 0	<27> 0
{Endocrine system}						
adrenal	leukemic cell infiltration		<10> 1	< 8> 0	<12> 0	<27> 0
	leukemic cell infiltration		<10> 1	< 8> 0	<12> 0	<27> 0
< a >						
a : Number of animals examined at the site						
b : Number of animals with lesion						

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 3

		Group Name	0 ppm	3 ppm	10 ppm	30 ppm
		No. of Animals on Study	10	8	12	27
Organ	Findings					
{Reproductive system}						
prostate	leukemic cell infiltration		<10> 2	< 8> 0	<12> 0	<27> 0
{Nervous system}						
brain	leukemic cell infiltration		<10> 3	< 8> 1	<12> 2	<27> 1
	metastasis:pituitary tumor		0	0	0	1
spinal cord	leukemic cell infiltration		<10> 2	< 8> 1	<12> 1	<27> 0
{Body cavities}						
pleura	metastasis:peritoneum tumor		<10> 0	< 8> 0	<12> 0	<27> 2
	metastasis:retroperitoneum tumor		0	0	0	1
< a > a : Number of animals examined at the site b b : Number of animals with lesion						

(JPT150)

BAIS3

## APPENDIX N 3

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR : SUMMARY

RAT : MALE : SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 1

		Group Name No. of Animals on Study	0 ppm 40	3 ppm 42	10 ppm 38	30 ppm 23
Organ	Findings					
{Respiratory system}						
lung	leukemic cell infiltration		<40> 1	<42> 0	<38> 0	<23> 0
	metastasis:thyroid tumor		0	0	0	1
{Digestive system}						
salivary gl	metastasis:subcutis tumor		<40> 0	<42> 0	<38> 1	<23> 0
liver	leukemic cell infiltration		<40> 2	<42> 0	<38> 0	<23> 2
{Urinary system}						
kidney	leukemic cell infiltration		<40> 0	<42> 0	<38> 0	<23> 1
{Nervous system}						
brain	metastasis:pituitary tumor		<40> 0	<42> 1	<38> 0	<23> 1
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					



## APPENDIX N 4

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR : SUMMARY

RAT : FEMALE: ALL ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 4

		Group Name No. of Animals on Study	0 ppm 50	3 ppm 50	10 ppm 49	30 ppm 50
Organ	Findings					
{Integumentary system/appandage}						
subcutis	leukemic cell infiltration		<50> 0	<50> 0	<49> 1	<50> 0
	metastasis:uterus tumor		0	1	0	0
{Respiratory system}						
lung	leukemic cell infiltration		<50> 2	<50> 3	<49> 1	<50> 6
	metastasis:uterus tumor		0	0	1	2
	metastasis:adrenal tumor		0	1	0	0
	metastasis:pancreas tumor		1	0	0	1
{Hematopoietic system}						
bone marrow	leukemic cell infiltration		<50> 1	<50> 1	<49> 1	<50> 3
	metastasis:uterus tumor		0	0	1	1
lymph node	leukemic cell infiltration		<50> 0	<50> 0	<49> 0	<50> 2
	metastasis:uterus tumor		0	0	1	1
thymus	metastasis:pancreas tumor		<50> 0	<50> 0	<49> 0	<50> 1
	metastasis:uterus tumor		0	0	0	2
spleen	metastasis:pancreas tumor		<50> 0	<50> 0	<49> 0	<50> 1
	metastasis:uterus tumor		0	0	0	1

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

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

Organ	Findings	Group Name No. of Animals on Study	0 ppm 50	3 ppm 50	10 ppm 49	30 ppm 50
{Circulatory system}						
heart			<50>	<50>	<49>	<50>
	metastasis:pancreas tumor		1	0	0	0
{Digestive system}						
stomach			<50>	<50>	<49>	<50>
	leukemic cell infiltration		1	0	1	0
	metastasis:pancreas tumor		1	0	0	0
small intes			<50>	<50>	<49>	<50>
	leukemic cell infiltration		0	0	0	1
	metastasis:pancreas tumor		1	0	0	0
large intes			<50>	<50>	<49>	<50>
	leukemic cell infiltration		0	0	0	1
	metastasis:uterus tumor		0	0	0	1
	metastasis:pancreas tumor		1	0	0	0
liver			<50>	<50>	<49>	<50>
	leukemic cell infiltration		3	3	1	5
	metastasis:uterus tumor		0	0	0	3
	metastasis:pancreas tumor		1	0	0	1
pancreas			<50>	<50>	<49>	<50>
	leukemic cell infiltration		0	0	1	0
	metastasis:spleen tumor		0	0	1	0
{Urinary system}						
kidney			<50>	<50>	<49>	<50>
	leukemic cell infiltration		0	0	0	1
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 6

Organ	Findings	Group Name No. of Animals on Study	0 ppm 50	3 ppm 50	10 ppm 49	30 ppm 50
{Urinary system}						
kidney	metastasis:uterus tumor		<50> 0	<50> 0	<49> 1	<50> 1
	metastasis:adrenal tumor		0	0	1	0
urin bladd	leukemic cell infiltration		<50> 0	<50> 0	<49> 1	<50> 0
{Endocrine system}						
adrenal	leukemic cell infiltration		<50> 1	<50> 0	<49> 0	<50> 2
	metastasis:uterus tumor		0	0	0	1
	metastasis:pancreas tumor		1	0	0	0
{Reproductive system}						
ovary	leukemic cell infiltration		<50> 0	<50> 1	<49> 0	<50> 0
	leukemic cell infiltration		<50> 0	<50> 1	<49> 1	<50> 0
{Nervous system}						
brain	leukemic cell infiltration		<50> 1	<50> 0	<49> 1	<50> 1
	metastasis:pituitary tumor		2	4	0	1
{Special sense organs/appendage}						
eye	leukemic cell infiltration		<50> 0	<50> 0	<49> 0	<50> 1

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

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 7

		Group Name	0 ppm	3 ppm	10 ppm	30 ppm
Organ_____	Findings_____	No. of Animals on Study	50	50	49	50
{Body cavities}						
mediastinum			<50>	<50>	<49>	<50>
	metastasis:pancreas tumor		1	0	0	0
peritoneum			<50>	<50>	<49>	<50>
	metastasis:spleen tumor		0	0	1	0
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					

(JPT150)

BAIS3

## APPENDIX N 5

HISTOLOGICAL FINDINGS : METASTASIS OF TUMOR : SUMMARY

RAT : FEMALE : DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 4

		Group Name No. of Animals on Study	0 ppm 9	3 ppm 12	10 ppm 10	30 ppm 18
Organ	Findings					
{Integumentary system/appandage}						
subcutis	leukemic cell infiltration		< 9> 0	<12> 0	<10> 1	<18> 0
	metastasis:uterus tumor		0	1	0	0
{Respiratory system}						
lung	leukemic cell infiltration		< 9> 1	<12> 2	<10> 1	<18> 3
	metastasis:uterus tumor		0	0	1	1
	metastasis:pancreas tumor		1	0	0	1
{Hematopoietic system}						
bone marrow	leukemic cell infiltration		< 9> 1	<12> 1	<10> 1	<18> 3
	metastasis:uterus tumor		0	0	1	0
lymph node	leukemic cell infiltration		< 9> 0	<12> 0	<10> 0	<18> 1
	metastasis:pancreas tumor		0	0	0	1
spleen	metastasis:uterus tumor		< 9> 0	<12> 0	<10> 0	<18> 2
	metastasis:pancreas tumor		0	0	0	1
{Circulatory system}						
heart	metastasis:pancreas tumor		< 9> 1	<12> 0	<10> 0	<18> 0

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

STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 5

		Group Name No. of Animals on Study	0 ppm 9	3 ppm 12	10 ppm 10	30 ppm 18
Organ	Findings					
{Digestive system}						
stomach	leukemic cell infiltration		< 9> 1	<12> 0	<10> 1	<18> 0
	metastasis:pancreas tumor		1	0	0	0
small intes	metastasis:pancreas tumor		< 9> 1	<12> 0	<10> 0	<18> 0
	metastasis:pancreas tumor		< 9> 1	<12> 0	<10> 0	<18> 0
large intes	metastasis:pancreas tumor		< 9> 1	<12> 0	<10> 0	<18> 0
	metastasis:pancreas tumor		< 9> 1	<12> 0	<10> 0	<18> 0
liver	leukemic cell infiltration		< 9> 1	<12> 2	<10> 1	<18> 3
	metastasis:uterus tumor		0	0	0	2
	metastasis:pancreas tumor		1	0	0	1
pancreas	leukemic cell infiltration		< 9> 0	<12> 0	<10> 1	<18> 0
	leukemic cell infiltration		< 9> 0	<12> 0	<10> 1	<18> 0
{Urinary system}						
kidney	leukemic cell infiltration		< 9> 0	<12> 0	<10> 0	<18> 1
	metastasis:uterus tumor		0	0	1	0
	metastasis:adrenal tumor		0	0	1	0
urin bladd	leukemic cell infiltration		< 9> 0	<12> 0	<10> 1	<18> 0
	leukemic cell infiltration		< 9> 0	<12> 0	<10> 1	<18> 0
{Endocrine system}						
adrenal	leukemic cell infiltration		< 9> 0	<12> 0	<10> 0	<18> 2
	leukemic cell infiltration		< 9> 0	<12> 0	<10> 0	<18> 2
< a >		a : Number of animals examined at the site				
b		b : Number of animals with lesion				



STUDY NO. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 6

Organ	Findings	Group Name No. of Animals on Study	0 ppm 9	3 ppm 12	10 ppm 10	30 ppm 18
{Endocrine system}						
adrenal	metastasis:uterus tumor		< 9> 0	<12> 0	<10> 0	<18> 1
	metastasis:pancreas tumor		1	0	0	0
{Reproductive system}						
ovary	leukemic cell infiltration		< 9> 0	<12> 1	<10> 0	<18> 0
	uterus		< 9> 0	<12> 1	<10> 1	<18> 0
{Nervous system}						
brain	leukemic cell infiltration		< 9> 1	<12> 0	<10> 1	<18> 1
	metastasis:pituitary tumor		1	1	0	0
{Special sense organs/appendage}						
eye	leukemic cell infiltration		< 9> 0	<12> 0	<10> 0	<18> 1
{Body cavities}						
mediastinum	metastasis:pancreas tumor		< 9> 1	<12> 0	<10> 0	<18> 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. : 0342  
 ANIMAL : RAT F344/DuCrj  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 2

		Group Name No. of Animals on Study	0 ppm 41	3 ppm 38	10 ppm 39	30 ppm 32
Organ	Findings					
{Respiratory system}						
lung			<41>	<38>	<39>	<32>
	leukemic cell infiltration		1	1	0	3
	metastasis:uterus tumor		0	0	0	1
	metastasis:adrenal tumor		0	1	0	0
{Hematopoietic system}						
lymph node			<41>	<38>	<39>	<32>
	leukemic cell infiltration		0	0	0	1
	metastasis:uterus tumor		0	0	0	1
{Digestive system}						
small intes			<41>	<38>	<39>	<32>
	leukemic cell infiltration		0	0	0	1
large intes			<41>	<38>	<39>	<32>
	leukemic cell infiltration		0	0	0	1
	metastasis:uterus tumor		0	0	0	1
liver			<41>	<38>	<39>	<32>
	leukemic cell infiltration		2	1	0	2
	metastasis:uterus tumor		0	0	0	1
pancreas			<41>	<38>	<39>	<32>
	metastasis:spleen tumor		0	0	1	0
{Urinary system}						
kidney			<41>	<38>	<39>	<32>
	metastasis:uterus tumor		0	0	0	1
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					

STUDY NO. : 0342  
ANIMAL : RAT F344/DuCrj  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 3

		Group Name	0 ppm	3 ppm	10 ppm	30 ppm
Organ	Findings	No. of Animals on Study	41	38	39	32
{Endocrine system}						
adrenal	leukemic cell infiltration		<41> 1	<38> 0	<39> 0	<32> 0
{Nervous system}						
brain	metastasis:pituitary tumor		<41> 1	<38> 3	<39> 0	<32> 1
{Body cavities}						
peritoneum	metastasis:spleen tumor		<41> 0	<38> 0	<39> 1	<32> 0
< a > a : Number of animals examined at the site						
b b : Number of animals with lesion						

(JPT150)

BAIS3

## APPENDIX O 1

### IDENTITY AND IMPURITY OF GLYCIDOL IN THE 2-YEAR INHALATION STUDY

## IDENTITY AND IMPURITY OF GLYCIDOL IN THE 2-YEAR INHALATION STUDY

Test Substance : Glycidol (Wako Pure Chemical Industries, Ltd.)

A. Lot No. : WTK5337

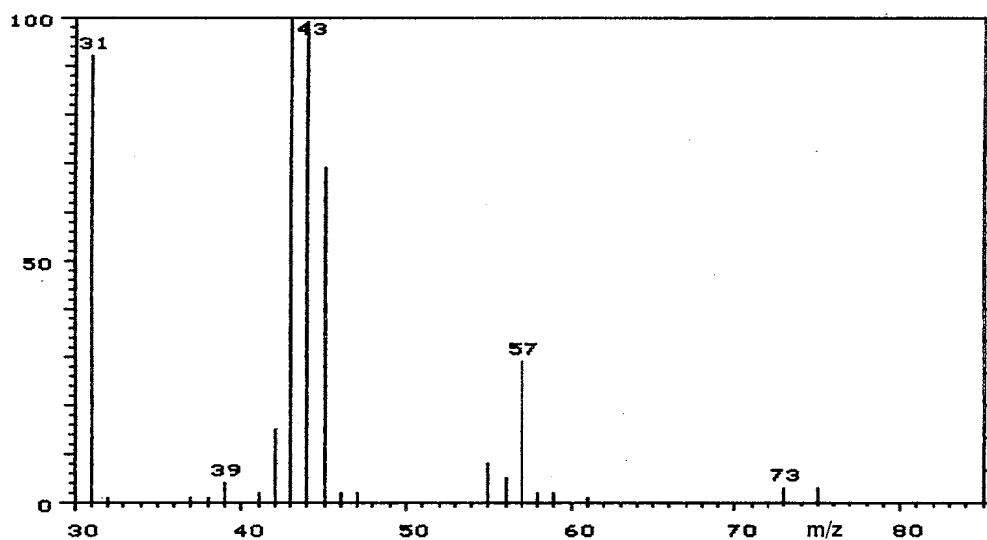
## 1. Spectral Data

Mass Spectrometry

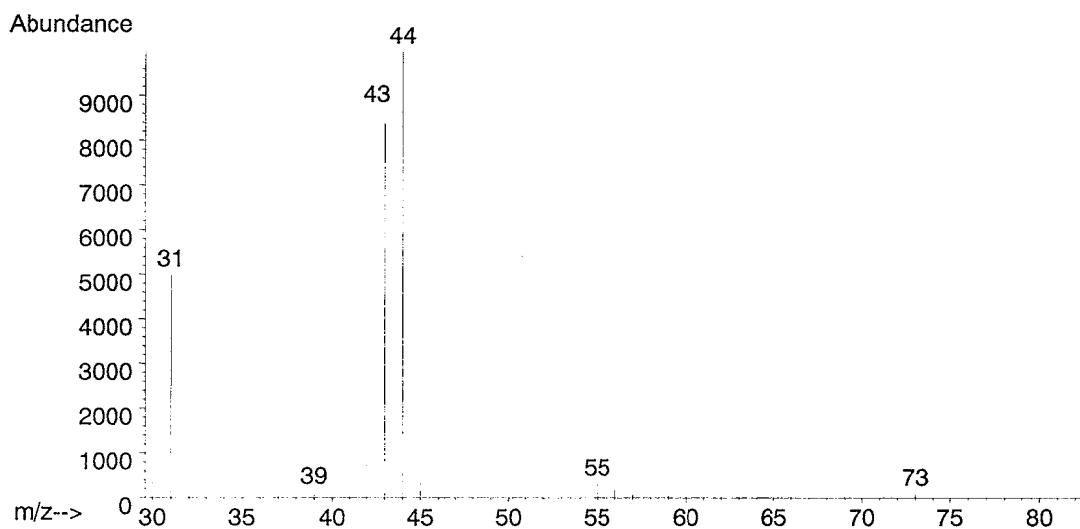
Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance



Mass Spectrum of Literature Data\*

Results: The mass spectrum was consistent with literature spectrum.

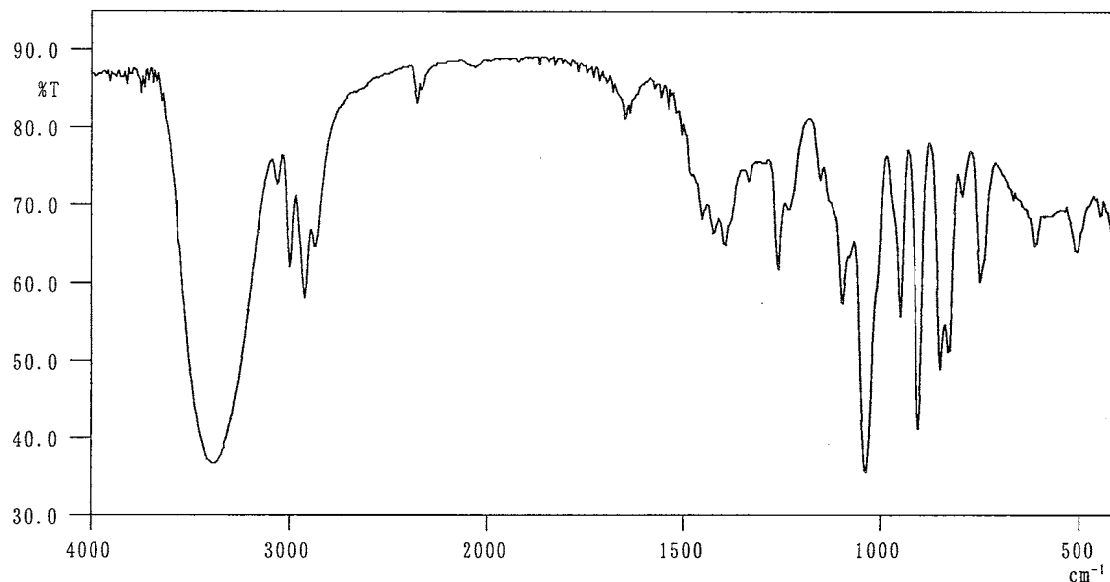
(\*Fred W. McLafferty (1994) Wiley Registry of Mass Spectral Data, 6th edition.  
John Wiley and Sons, Inc. (U.S.), Entry Number 1733)

Infrared Spectrometry

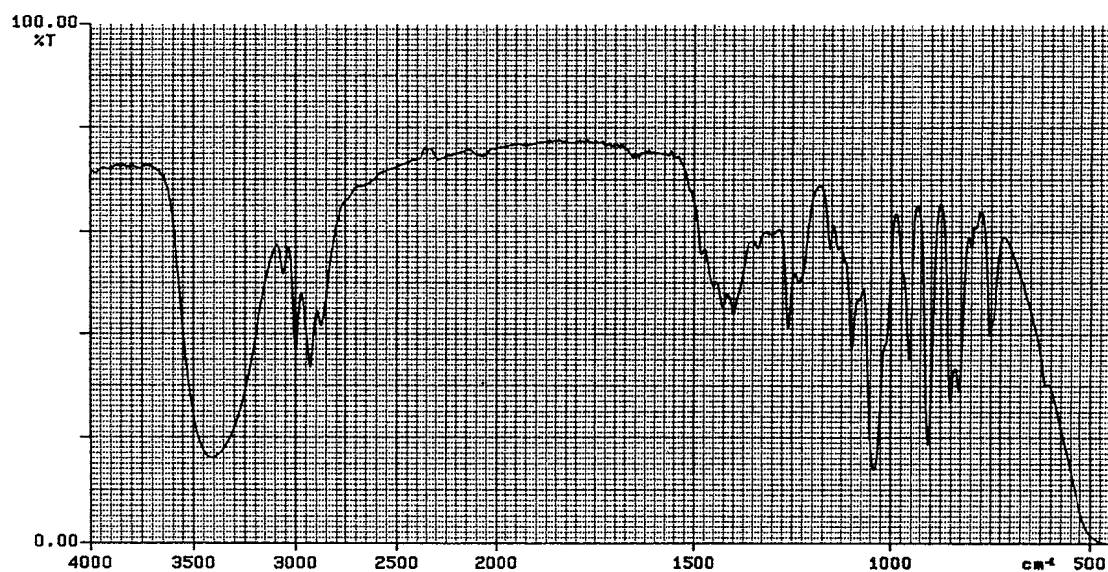
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 4  $\text{cm}^{-1}$



Infrared Spectrum of Test Substance



Infrared Spectrum of Literature Data\*

Results: The infrared spectrum was consistent with literature spectrum.  
(\*Performed by Wako Pure Chemical Industries, Ltd.)

## 2. Impurity

Instrument : Hewlett Packard 5890A Gas Chromatograph  
Column : Methyl Silicone (0.53 mm  $\phi$   $\times$  60 m)  
Column Temperature: 150 ° C  
Flow Rate : 10 mL/min  
Detector : FID (Flame Ionization Detector)  
Injection Volume : 1  $\mu$ L

Sample Name	Peak No.	Area (%)	Peak Name
Test Substance	1	0.207	Material which cannot be identified
	2	0.087	Material which cannot be identified
	3	99.706	glycidol

Results: Gas chromatography indicated one major peak (peak No.3) and two impurity peaks. These two impurity peaks(peaks No.1 and No.2) can not be identified. The amounts in the test substance were 0.207% and 0.087%.

3. Conclusion: The test substance was identified as glycidol by mass spectrum and infrared spectrum. Gas chromatography indicated one major peak(peak No.3) and two impurity peaks. These two impurity peaks(peaks No.1 and No.2) can not be identified. The amounts in the test substance were 0.207% and 0.087%.



B. Lot No. : PAL5331

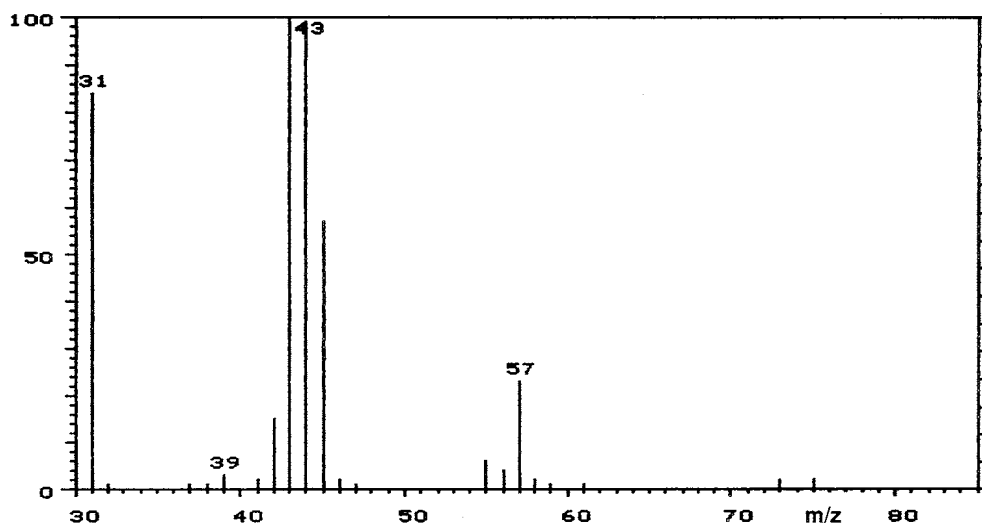
# 1. Spectral Data

## Mass Spectrometry

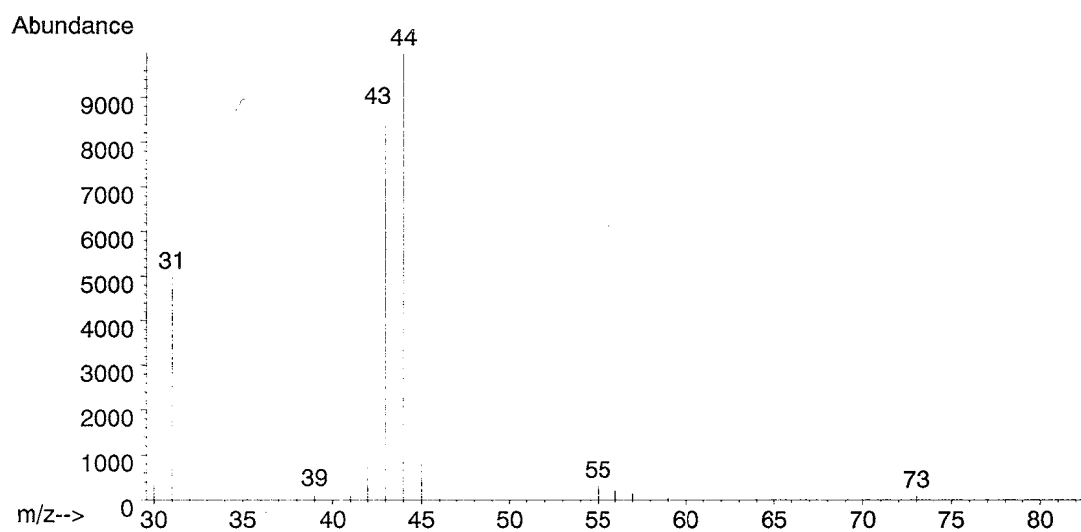
Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance



Mass Spectrum of Literature Data\*

Results: The mass spectrum was consistent with literature spectrum.

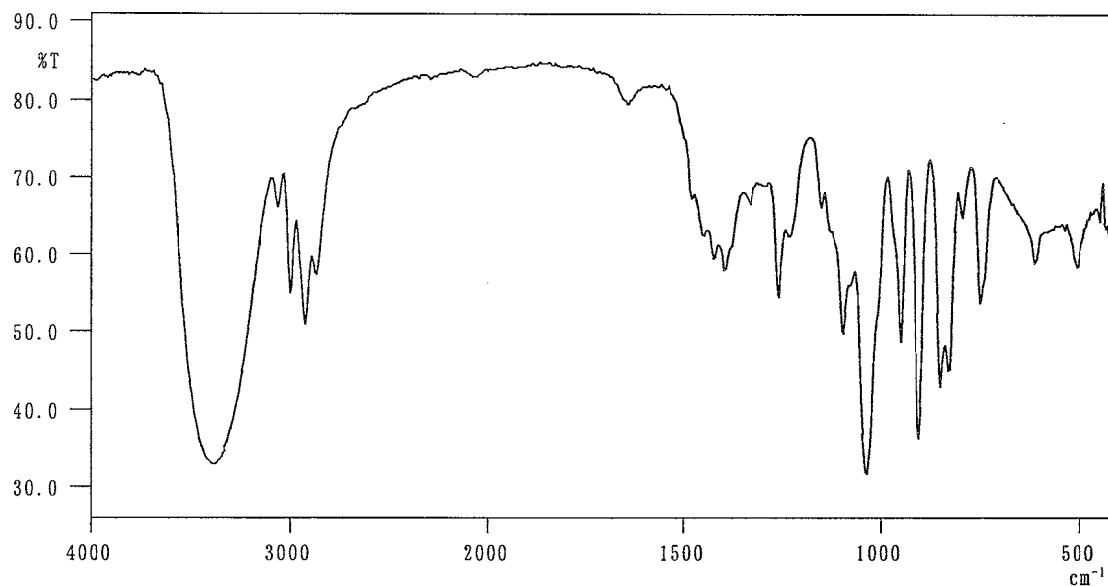
(\*Fred W. McLafferty (1994) Wiley Registry of Mass Spectral Data, 6th edition.  
John Wiley and Sons, Inc. (U.S.), Entry Number 1733)

Infrared Spectrometry

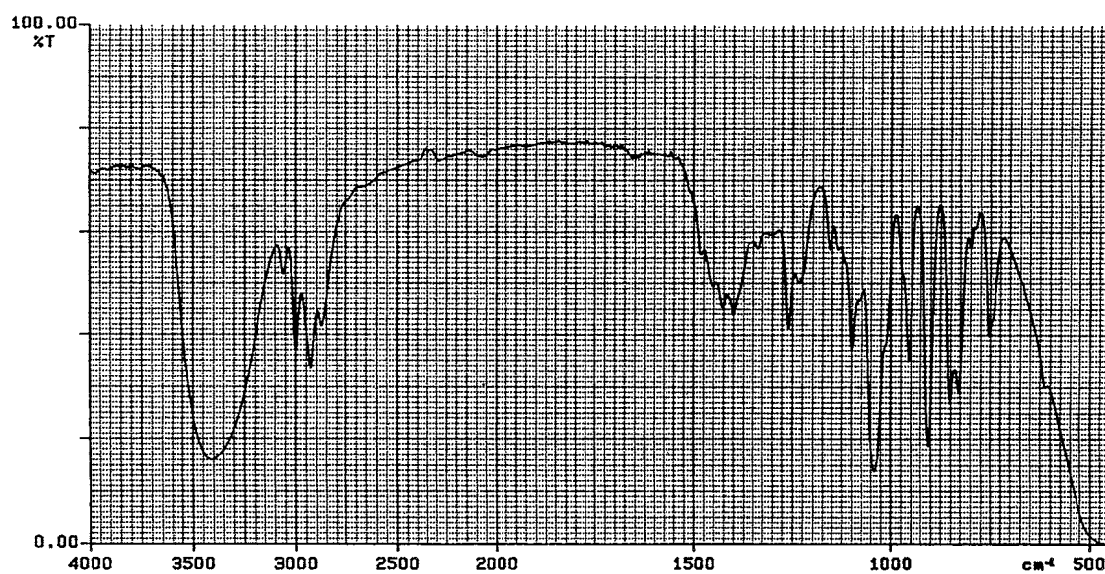
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 4  $\text{cm}^{-1}$



Infrared Spectrum of Test Substance



Infrared Spectrum of Literature Data\*

Results: The infrared spectrum was consistent with literature spectrum.  
(\*Performed by Wako Pure Chemical Industries, Ltd.)

## 2. Impurity

Instrument : Hewlett Packard 5890A Gas Chromatograph  
Column : Methyl Silicone (0.53 mm $\phi$   $\times$  60 m)  
Column Temperature: 150 °C  
Flow Rate : 10 mL/min  
Detector : FID (Flame Ionization Detector)  
Injection Volume : 1  $\mu$ L

Sample Name	Peak No.	Area (%)	Peak Name
Test Substance	1	0.215	Material which cannot be identified
	2	0.083	Material which cannot be identified
	3	99.702	glycidol

Results: Gas chromatography indicated one major peak (peak No.3) and two impurity peaks. These two impurity peaks(peaks No.1 and No.2) can not be identified. The amounts in the test substance were 0.215% and 0.083%.

3. Conclusion: The test substance was identified as glycidol by mass spectrum and infrared spectrum. Gas chromatography indicated one major peak(peak No.3) and two impurity peaks. These two impurity peaks(peaks No.1 and No.2) can not be identified. The amounts in the test substance were 0.215% and 0.083%.

C. Lot No. : CKP4929

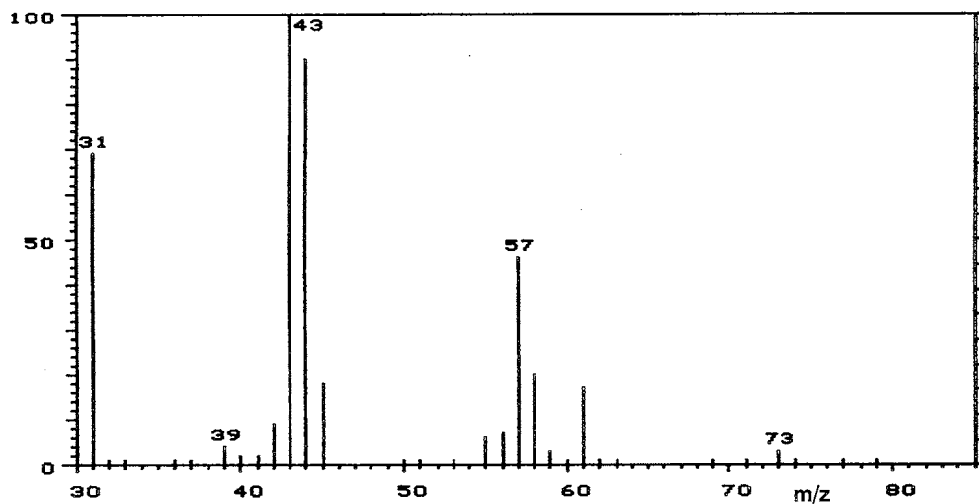
1. Spectral Data

Mass Spectrometry

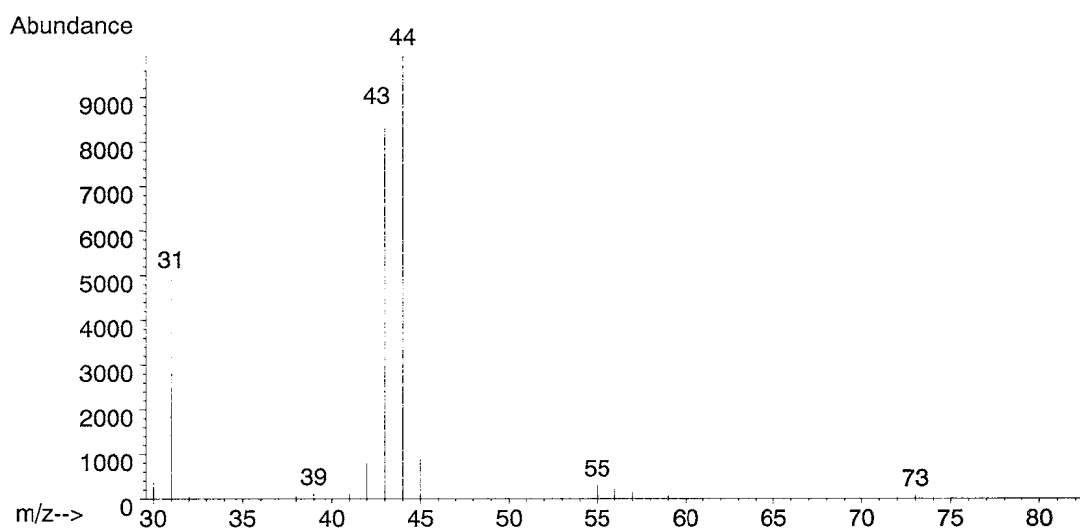
Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance



Mass Spectrum of Literature Data\*

Results: The mass spectrum was consistent with literature spectrum.

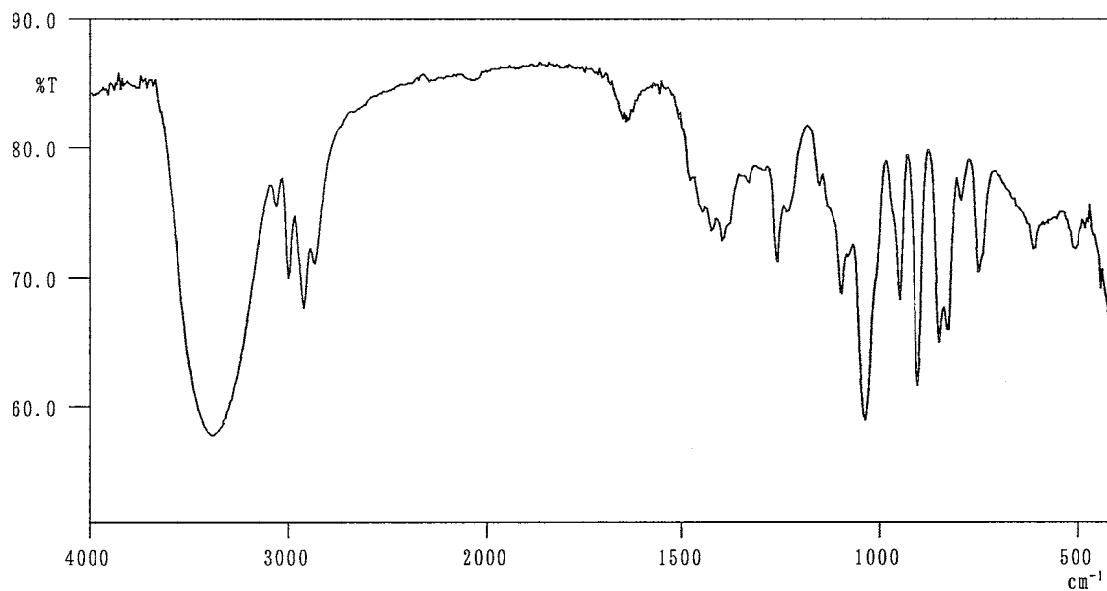
(\*Fred W. McLafferty (1994) Wiley Registry of Mass Spectral Data, 6th edition.  
John Wiley and Sons, Inc. (U.S.), Entry Number 1733)

Infrared Spectrometry

Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 4  $\text{cm}^{-1}$



Infrared Spectrum of Test Substance



Infrared Spectrum of Literature Data\*

Results: The infrared spectrum was consistent with literature spectrum.  
(\*Performed by Wako Pure Chemical Industries, Ltd.)

## 2. Impurity

Instrument : Hewlett Packard 5890A Gas Chromatograph  
Column : Methyl Silicone (0.53 mm  $\phi$   $\times$  60 m)  
Column Temperature: 150 °C  
Flow Rate : 10 mL/min  
Detector : FID (Flame Ionization Detector)  
Injection Volume : 1  $\mu$ L

Sample Name	Peak No.	Area (%)	Peak Name
Test Substance	1	0.220	Material which cannot be identified
	2	0.087	Material which cannot be identified
	3	99.693	glycidol

Results: Gas chromatography indicated one major peak (peak No.3) and two impurity peaks. These two impurity peaks(peaks No.1 and No.2) can not be identified. The amounts in the test substance were 0.220% and 0.087%.

3. Conclusion: The test substance was identified as glycidol by mass spectrum and infrared spectrum. Gas chromatography indicated one major peak(peak No.3) and two impurity peaks. These two impurity peaks(peaks No.1 and No.2) can not be identified. The amounts in the test substance were 0.220% and 0.087%.

## APPENDIX O 2

### STABILITY OF GLYCIDOL IN THE 2-YEAR INHALATION STUDY

## STABILITY OF GLYCIDOL IN THE 2-YEAR INHALATION STUDY

Test Substance : Glycidol (Wako Pure Chemical Industries, Ltd.)

A. Lot No. : WTK5337

1. Sample : This lot was used from 1997.9.29 to 1998.8.5. Test substance was stored at a temperature below 20°C.

2. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : Methyl Silicone ( 0.53 mm $\phi$   $\times$  60 m)

Column Temperature: 150° C

Flow Rate : 10 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1  $\mu$ L

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
1997.09.26	1	1.914	0.207
	2	2.217	0.087
	3	2.560	99.706
1998.08.06	1	1.901	0.217
	2	2.205	0.088
	3	2.549	99.695

Results: Gas chromatography indicated one major peak (peak No.3) and two impurities (peaks No.1 and No.2 < 0.4% of total area) analyzed on 1997.9.26 and one major peak (peak No.3) and two impurities (peaks No.1 and No.2 < 0.4% of total area) analyzed on 1998.8.6. No new trace impurity peak in the test substance analyzed on 1998.8.6 was detected.

3. Conclusions: The test substance was stable for about 1 year at a temperature below 20°C.



B. Lot No. : PAL5331

1. Sample : This lot was used from 1998.8.6 to 1999.4.6. Test substance was stored at a temperature below 20°C.

2. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : Methyl Silicone ( 0.53 mm  $\phi$   $\times$  60 m)

Column Temperature: 150° C

Flow Rate : 10 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1  $\mu$ L

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
1998.07.27	1	1.908	0.215
	2	2.210	0.083
	3	2.554	99.702
1999.04.07	1	1.902	0.218
	2	2.203	0.086
	3	2.545	99.696

Results: Gas chromatography indicated one major peak (peak No.3) and two impurities (peaks No.1 and No.2 < 0.4% of total area) analyzed on 1998.7.27 and one major peak (peak No.3) and two impurities (peaks No.1 and No.2 < 0.4% of total area) analyzed on 1999.4.7. No new trace impurity peak in the test substance analyzed on 1999.4.7 was detected.

3. Conclusions: The test substance was stable for about 8 months at a temperature below 20°C.

C. Lot No. : CKP4929

1. Sample : This lot was used from 1999.4.7 to 1999.9.24. Test substance was stored at a temperature below 20°C.

2. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : Methyl Silicone ( 0.53 mm  $\phi$   $\times$  60 m)

Column Temperature: 150° C

Flow Rate : 10 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1  $\mu$ L

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
1999.04.06	1	1.900	0.220
	2	2.205	0.087
	3	2.547	99.693
1999.10.28	1	1.897	0.220
	2	2.203	0.081
	3	2.544	99.699

Results: Gas chromatography indicated one major peak (peak No.3) and two impurities (peaks No.1 and No.2 < 0.4% of total area) analyzed on 1999.4.6 and one major peak (peak No.3) and two impurities (peaks No.1 and No.2 < 0.4% of total area) analyzed on 1999.10.28. No new trace impurity peak in the test substance analyzed on 1999.10.28 was detected.

3. Conclusions: The test substance was stable for about 7 months at a temperature below 20°C.

APPENDIX P 1

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

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

Group Name	Concentration (ppm)	
	Mean	$\pm$ S.D.
0ppm	0.0	$\pm$ 0.0
3ppm	3.0	$\pm$ 0.1
10ppm	10.0	$\pm$ 0.2
30ppm	29.9	$\pm$ 0.6

## APPENDIX P 2

### ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL

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

Group Name	Temperature(°C)			Humidity(%)			Ventilation Rate (L/min)			Air Changes (time/h)	
	Mean	±	S.D.	Mean	±	S.D.	Mean	±	S.D.	Mean	
0ppm	22.2	±	0.2	54.8	±	1.1	1521.2	±	10.6	12.0	
3ppm	22.5	±	0.3	54.1	±	1.2	1516.9	±	14.3	12.0	
10ppm	22.1	±	0.2	54.5	±	1.8	1521.5	±	10.3	12.0	
30ppm	22.1	±	0.2	53.3	±	2.4	1515.5	±	10.5	12.0	

## APPENDIX Q

METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY  
AND BIOCHEMISTRY IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL

METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY  
IN THE 2-YEAR INHALATION STUDY OF GLYCIDOL

Item	Method	Unit	Decimal place
<b>Hematology</b>			
Red blood cell (RBC)	Light scattering method <sup>1)</sup>	$\times 10^6/\mu\text{L}$	2
Hemoglobin(Hgb)	Cyanmethemoglobin method <sup>1)</sup>	g/dL	1
Hematocrit(Hct)	Calculated as $\text{RBC} \times \text{MCV} / 10$ <sup>1)</sup>	%	1
Mean corpuscular volume(MCV)	Light scattering method <sup>1)</sup>	fL	1
Mean corpuscular hemoglobin(MCH)	Calculated as $\text{Hgb} / \text{RBC} \times 10$ <sup>1)</sup>	pg	1
Mean corpuscular hemoglobin concentration (MCHC)	Calculated as $\text{Hgb} / \text{Hct} \times 100$ <sup>1)</sup>	g/dL	1
Platelet	Light scattering method <sup>1)</sup>	$\times 10^3/\mu\text{L}$	0
White blood cell(WBC)	Light scattering method <sup>1)</sup>	$\times 10^3/\mu\text{L}$	2
Differential WBC	Pattern recognition method <sup>2)</sup> (Wright staining)	%	0
<b>Biochemistry</b>			
Total protein(TP)	Biuret method <sup>3)</sup>	g/dL	1
Albumin (Alb)	BCG method <sup>3)</sup>	g/dL	1
A/G ratio	Calculated as $\text{Alb} / (\text{TP} - \text{Alb})$ <sup>3)</sup>	—	1
T-bilirubin	Alkaline azobilirubin method <sup>3)</sup>	mg/dL	2
Glucose	GlcK•G-6-PDH method <sup>3)</sup>	mg/dL	0
T-cholesterol	CE•COD•POD method <sup>3)</sup>	mg/dL	0
Triglyceride	LPL•GK•GPO•POD method <sup>3)</sup>	mg/dL	0
Phospholipid	PLD•ChOD•POD method <sup>3)</sup>	mg/dL	0
Glutamic oxaloacetic transaminase (GOT)	JSCC method <sup>3)</sup>	IU/L	0
Glutamic pyruvic transaminase (GPT)	JSCC method <sup>3)</sup>	IU/L	0
Lactate dehydrogenase (LDH)	SFBC method <sup>3)</sup>	IU/L	0
Alkaline phosphatase (ALP)	GSCC method <sup>3)</sup>	IU/L	0
$\gamma$ -Glutamyl transpeptidase ( $\gamma$ -GTP)	L- $\gamma$ -Glutamyl-p-nitroanilide method <sup>3)</sup>	IU/L	0
Creatine phosphokinase (CPK)	JSCC method <sup>3)</sup>	IU/L	0
Urea nitrogen	Urease•GLDH method <sup>3)</sup>	mg/dL	1
Creatinine	Jaffe method <sup>3)</sup>	mg/dL	1
Sodium	Ion selective electrode method <sup>3)</sup>	mEq/L	0
Potassium	Ion selective electrode method <sup>3)</sup>	mEq/L	1
Chloride	Ion selective electrode method <sup>3)</sup>	mEq/L	0
Calcium	OCPC method <sup>3)</sup>	mg/dL	1
Inorganic phosphorus	PNP•XOD•POD method <sup>3)</sup>	mg/dL	1

1) Automatic blood cell analyzer (Technicon H•1 : Bayer Corporation)

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

3) Automatic analyzer (Hitachi 7070 : Hitachi, Ltd.)