o-フェニレンジアミン二塩酸塩のマウスを用いた 経口投与によるがん原性試験(混水試験)報告書

試験番号:0372

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APPENDICES

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APPENDIX A 1

CLINICAL OBSERVATION: SUMMARY, MOUSE: MALE

(2-YEAR STUDY)

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

STUDY NO. : 0372

SEX : MALE

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Clinical sign	Group Name	Admini	stration We	eek-day											
7,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		1-7	2-7	3-7	4-7	5-7	6-7	7–7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	. 0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 բբա	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	. 0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	· 2000 ppm	0	0	0	0	0	0	0	0	0	0	0	ō	Ö	0
PILOERECTION	Control	0	1	1	0	1	i	ı	1	1	1	0	0	0	0
	500 ppm	0	0	0	0	0	0	1	0	Ō	ō	0	0	ō	ō
	1000 ppm	0	0	0	0	1	1	1	1	1	1	0	0	ō	ō
	2000 ppm	0	0	2	0	1	1	2	2	3	2	2	2	2	2
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	Ō	0	Õ
	1000 ppm	0	0	0	0	0	0	0	0	Õ	Ö	ŏ	0	0	0
	2000 ppm	0	0	0	0	0	Ō	Ō	ő	Ö	ŏ	ő	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	ō	Ō	Ö	ŏ	ō	0	Ŏ	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	Ö	0	0	0	0	0
	2000 ppm	0	0	ō	Ö	Ö	0	0	0	•	•	v	•	v	U

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STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admini	istration W	eek-day _											
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
EATII	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DRIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	ō	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	ő	0	0	0	0
INCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	Ö	Ö	Ö	0	0	0	Ö	0
	1000 ppm	0	0	0	0	0	0	Ö	Ö	Ö	0	0	0	0	0
	2000 ppm	0	0	0	0	0	Ô	0	Ö	Ö	ő	ŏ	0	0	0
ASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	Ō	0	ō	ŏ	Ö	Ö	0	0
	1000 ppm	0	0	0	0	0	Ö	Ö	0	o o	o o	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	Ö	Ö	Ö	0	0	0
LOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	ō	Ö	Ö	Õ	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	Ō	0	ŏ	ő	Ö	0	0	0	0
	2000 ppm	1	1	1	0	0	0	Ö	0	0	0	0	0	0	0
ROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	Ö	Ö	Ő	0	0	0	0	0	0	0
	1000 ppm	ō	Ŏ	Ö	Ő	0	0	0	0	0	0	0	0		
	2000 ppm	ő	ő	ő	0	0	0	0	0	0	0	0	0	0 0	0
DILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	٥	0	•	•
	500 ppm	0	Ŏ	o	0	0	0	0	0		0	0	0	0	0
	1000 ppm	Ŏ	0	0	0	0	0			0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	Ū	U	U	U	U	U	0	0	0	0	0	0	0	0

 $\sum_{i=1}^{n} \frac{1}{i}$

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE

Clinical sign	rol ppm ppm ppm ppm ppm ppm ppm p	0 0 0 0 0 0	30-7 0 0 0 0 0	0 0 0 0 0	32-7 0 0 0 0	32-7 0 0 0	33-7 0 0	34-7 0 0	35-7 0 0	36-7 0 0	37-7	38-7	39-7	40-7	41-7
1000 1000	opm opm rol opm	0 0 0 0	0 0 0	0 0 0	0 0	0	0							0	0
SOO 1000 1	opm opm rol opm	0 0 0 0	0 0 0	0 0 0	0 0	0	0							U	U
1000 2000	opm rol ppm ppm ppm ppm ppm ppm	0 0 0 0	0 0 0	0	0	0		U	£)						
### 2000 p #################################	rol ppm ppm ppm ppm ppm	0 0 0	0 0 0	0				_			0	0	1	1	1
MORIBUND SACRIFICE Conta 500 r 1000 r 2000 r 2000 r 1000 r	rol ppm ppm ppm rol ppm	0 0 0	0	0	υ		0	0	0	0	0	0	0	0	0
1000 1000	ppm ppm ppm rol ppm	0	0			v	0	0	0	0	0	0	1	1	1
1000 2000	ppm ppm rol ppm	0		^	0	0	0	0	0	0	0	0	0	0	0
2000 1 00COMOTOR MOVEMENT DECR Control 1000 1 2000 1	ppm rol ppm		0	0	0	0	0	0	0	0	0	0	0	0	0
JOCOMOTOR MOVEMENT DECR 500 p 1000 p 2000 p 100CHBACK POSITION Contact	rol ppm	0		0	0	0	0	0	0	0	0	0	0	0	0
1000 1000	ppm		0	0	0	0	0	0	0	0	0	0	0	0	0
500 1000 1	ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1000 2000 2000 1000		0	Ŏ	Ö	0	0	ō	Ö	Ö	0	Ö	Ö	0	Ö	0
2000 1 1 1 1 1 1 1 1 1	F- J-111	Ö	Ö	0	0	0	Ő	0	0	0	0	0	0	0	0
UNCHBACK POSITION Contact		0	0	0	0	0	0	0	0	0	0	0	0	0	0
500 1000 1000 2000 1	իիա	v	U	U	U	v	U	U	U	U	U	U	U	U	Ü
1000 1 2000 1 ASTING Cont. 500 1 1000 1 2000 1		0	0	0	0	0	0	0	0	0	0	0	0	0	0
2000 1 ASTING Conti 500 1 1000 2 2000 1	ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ASTING Continuous Cont		0	0	0	0	0	0	0	0	0	0	0	0	0	0
500 p 1000 p 2000 p ILOERECTION Conti	ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1000 g 2000 g ILOERECTION Conti	rol	0	0	0	0	0	0	. 0	0	0	0	0	0	0	0
2000 j	ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTION Cont	ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	ro1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
500 1	ppm	0	0	0	0	Ō	Ö	1	1	1	1	1	0	Ö	o o
1000		0	0	Ŏ	0	Ö	0	Ô	Ô	Ô	0	Ô	0	0	0
2000		0	0	0	0	0	0	0	0	0	0	0	0	0	0
	P.P.III	•	v	٧	v	v	Ū	v	v	v	v	v	v	U	U
ROG BELLY Cont		0	0	0	0	0	0	0	0	0	0	0	0	0	0
500	ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	. 0
1000		0	0	0	0	0	0	0	0	0	0	0	0	0	0
2000	ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OILED PERI GENITALIA CONT	rol	0	0	0	0	0	0	0	0	0	0	0	0	0	0
500		ŏ	ō	0	0	0	0	Ö	0	0	0	0	0	0	0
1000		Ŏ	0	Ö	0	0	0	0	0	0	0	0	0	0	0
2000	E-Free	ő	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE PAGE: 4

Clinical sign	Group Name	Admini	stration W	eek-day											
		42-7	43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-1
EATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
ORTBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0.	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TUNCIBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
ASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
•	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
ROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-day _											
		56-7 	57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7
				_					_	_					
DEATII	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	1	1	2	2	2	2	2	2	3	3	3	3	3	3
	1000 ppm	0	0	0	0	1	1	1	1	1	1	1	l	1	1
	2000 ppm	1	I	1	1	1	1	1	1	1	1	1	1	1	1
ORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	ō	ō
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	Ö	0	0	0	0	0	Ŏ	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	ō
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	ō
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	Ō	0	ō	ō	ŏ	Ŏ	Ö	ŏ	Ö
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-day											
	-	70-7	71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-1
CAMI	0 . 1	•	•		•	•								_	
EATH	Control	0	0	0	0	0	0	0	0	0	1	2	2	2	2
	500 ppm	4	4	4	4	4	4	4	5	5	5	6	6	6	6
	1000 ppm	1	1	I	1	1	1	I	1	1	1	1	l	l	1
	2000 ppm	1	1	1	1	1	1	1	2	2	2	2	2	2	2
ORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	mqq 0001	0	0	0	. 0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	1	0	1	1	1	1	i	1	1	1	ŏ	0	0	0
	1000 ppm	0	0	0	0	õ	ō	Ō	ō	Ô	Ô	Õ	0	0	0
	2000 ppm	0	0	1	1	ī	1	1	ō	0	ő	Ö	ő	0	1
ROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	i	0	Ö	ŏ	0	Ô	0	0
	1000 ppm	0	0	0	ō	ő	Ö	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	ō	Ö	ŏ	o	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	Ŏ	Ö	ō	Ö	ŏ	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	Ö	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	Ö	0	0	0	o o	Ô	0	0	0	0	0	0	0

ANIMAL : MOUSE Crj:BDF1

2000 ppm

Control

500 ppm

1000 ppm

2000 ppm

REPORT TYPE : A1 104

STUDY NO. : 0372

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-day _											
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
DEATH	Control	2	2	2	2	2	2	2	2	2	3	4	5	6	6
	500 ppm	6	6	7	7	7	7	7	7	7	9	9	9	10	10
	1000 ppm	1	1	1	1	1	1	1	1	1	2	2	2	2	3
	2000 ppm	2	2	3	4	4	5	5	5	6	6	7	7	7	7
ORIBUND SACRIFICE	Control	0	0	0	0	1	1	1	,	,	1	1	1	,	0
monthon bhont for	500 ppm	0	0	0	0	0	1	0	1	1	1	1	1	1	2
	1000 ppm	0	0	0	1	,	1	,	1	1	U	υ		0	U
	2000 ppm	0	0	0	0	0	1	2	2	2	2	2	2	2	3
	2000 ppm	•	•	v	v	v		2	2	2	2	4	4	4	3
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ō
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	500 ppm	ñ	0	n	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	ů	0	0	0	0	0	1	1	1	0	0	0	n	0

WASTING

PILOERECTION

FROG BELLY

SOILED PERI GENITALIA

PAGE: 7

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ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0372

SEX : MALE

Clinical sign	Group Name	Admini	istration	Week-day				
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
						····		
DEATH	Control	7	8	8	9	9	10	10
	500 ppm	10	10	10	10	10	10	10
	1000 ppm	3	4	4	7	7	7	7
	2000 ppm	7	7	7	7	7	8	8
MODIFIED CASPARAGE					_			
MORIBUND SACRIFICE	Control	2	2	2	2	2	2	2
	500 ppm	0	0	0	1	1	1	2
	1000 ppm	1	1	1	1	1	1	1
	2000 ppm	3	3	3	3	3	3	3
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0
TOTAL MOTERATE PROT	500 ppm	Ő	0	0	1	0	ő	0
	1000 ppm	ő	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0
	2000 ppili	•	v	v	v	v	v	v
HUNCHBACK POSITION	Control	1	0	0	1	1	1	0
	500 թբա	0	0	0	0	0	0	0
	mqq 0001	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0
WASTING	Control	0	0	0	1	1	1	0
WWO I THO	500 ppm	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0
	2000 ppiii	v	v	v	V	v	v	v
PILOERECTION	Control	2	1	2	2	2	l	2
	500 ppm	0	0	0	0	2	2	1
	1000 ppm	1	1	1	0	0	0	0
	2000 ppm	0	0	0	0	1	0	0
FROG BELLY	Control	0	0	0	1	9	_	9
i nod pibbbi	500 ppm			0	1	2	5	2
		0	0	0	0	0	3	1
	1000 ppm	0	0 0	0 0	0	0	1	0
	2000 ppm	U	U	U	U	0	1	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	1	0
	1000 ppm	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Adminis	tration W	eek-day					-						
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
EXOPIITIIALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ррт	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	mege 0001	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TITIE TO MENO	500 ppm	Ö	Ö	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	Ô	ō	ō	0	0	0	0	0	0	0	0	0	0	0
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	. 0	0	0	0
··· · · · · ·	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ррт	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

M. MANDIBULAR

Control 500 ppm

1000 ppm

2000 ppm

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE

SEX : MALE															PAGE :	10
Clinical sign	Group Name	Admini	stration P	Yeek-day												
•		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7	

Clinical sign	Group Name	Admini	stration W	eek-day _											
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
(OPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
VOLITITACMOS	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		-						-		0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	U	U	U	U	U	U	U	U	U
YE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
XTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	muq 0001	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NTERNAL MASS	Control	0	0	0	0	0	0	0	0	1	1	1	1	1	1
	500 ppm	0	0	1	1	1	1	1	1	1	1	1	1	1	1
	1000 ppm	0	1	1	1	1	1	1	1	1	1	1	i	1	1
	2000 ppm	0	0	1	1	1	1	1	1	1	1	1	I	I	1
. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
L EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	Ů.	0	Ö	Ö	0	0	Ö	0	0	0	0	0
	2000 ppm	ů 0	0	0	0	0	0	0	0	0	0	0	0	0	0
		•	•	v	v	v	v	v	٠	v	v	v	v	v	U
A. MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 բբա	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

STUDY NO. : 0372

SEX : MALE

linical sign	Group Name	Admini 29-7	istration W 30-7	eek-day 31-7	32-7	32-7	33-7	34-7	35-7	36-7	07.7	00.7	00.7	40.7	
		29-1		31-1	36-1	32-1	33-1	34-7	35-1	30-7	37-7	38-7	39-7	40-7	41-7
XOPIITIIALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	ō	0
E OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	Ö	0	0	Õ	Ö	Ŏ	0	0	0
	1000 ppm	Ö	Ö	ŏ	Ö	ŏ	Ö	Ö	Ö	Ö	Ö	0	0	0	0
	2000 թթո	Ö	Ö	ő	0	Ö	ő	ő	0	0	0	0	0	0	0
ATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	•
	500 ppm	0	0	0	0	0	0	0	0	0 0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0			-	0	0	0
	2000 ppm	0	0	0	0					0	0	0	0	0	0
	2000 ppm	U	U	U	U	0	0	0	0	0	0	0	0	0	. 0
TERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 բբա	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 թա	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NTERNAL MASS	Control	1	1	1	0	1	1	1	1	1	1	1	1	1	1
	500 ppm	1	1	1	0	1	1	1	1	1	1	1	i	1	1
	1000 ppm	2	2	2	0	2	2	2	2	2	3	3	3	3	3
	2000 ppm	1	1	1	0	1	1	1	1	1	1	0	0	0	0
NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	Ō	0	Ö	Ö	0	0	Ö	ő	0
	1000 ppm	0	0	0	Ö	Ö	Ö	0	0	0	0	0	0	0	0
	2000 ppm	Ŏ	Ö	0	ő	o	ō	0	0	0	0	0	0	0	0
EYE	Control	0	0	0	0	0	0	0	0	0	٥	0	0	0	•
	500 ppm	0	0	0	0	0			0	0	0	0	0	0	0
	1000 ppm	0	0	0	0		0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0		0 0	0	0	0	0	0	0	0	0	0
	2000 ppm	U	υ	U	0	U	0	0	0	0	0	0	0	0	0
MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0372

SEX : MALE

linical sign	Group Name	Admini	stration W	eek-dav											
		42-7	43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7
XOPIITIIALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MONITHIALMOS	Control 500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
								-				0			
	1000 ppm	0	0	0 0	0 0	0	0 0	0	0 0	0	0	0	0 0	0 0	0
	2000 ppm	U	U	U	U	U	U	U	U	U	U	U	U	U	U
YE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	mqq 003	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	ō	0	0	0	Ō	0	Ō	0	Ö	0
	2000 ppm	0	0	Ō	Ö	ō	0	0	Ö	ō	ō	0	ō	Ŏ	ō
	FF	•	•	•	•	•	•	•	-	•	-	•	-	-	-
ATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
KTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL OF MELOD	500 ppm	0	ŏ	0	Ö	Ö	Ö	0	ő	0	Ö	Ö	0	Ö	0
	1000 ppm	0	0	0	0	0	Ŏ	0	0	0	0	0	Ö	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppss	•	v	v	v	v	V	Ū	v	v	v	U	Ū	v	Ū
NTERNAL MASS	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	500 ppm	I	I	1	1	1	1	1	1	1	1	1	1	1	1
	1000 ppm	3	3	3	3	3	3	3	3	3	3	3	3	4	4
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0		0			
	2000 ppm	v	U	V	U	U	U	U	U	U	0	U	0	0	0
. EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	^
· man DIDODIN	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0		0
	1000 ppm	0	0	0	0							-		0	0
	2000 ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
	2000 ppm	U	U	V	0	0	0	0	0	0	0	0	0	0	0

 $\frac{1}{2}$

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-day											
		56-7	57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-1
EXOPIITHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
YE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	O
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	C
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	muq 0001	0	0	0	0	0	0	1	1	1	1	1	1	1	i
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
INTERNAL MASS	Control	1	1	1	1	1	1	1	1	1	1	1	1	2	2
	500 ррш	1	1	1	2	2	2	2	2	1	1	1	1	1	1
	1000 ppm	4	4	4	4	4	4	3	3	3	3	3	3	5	4
	2000 ppm	0	0	0	0	0	. 0	0	0	0	0	0	0	0	C
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	mqq 003	0	0	0	0	0	0	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
M. EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	4
M. MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	4

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0372

SEX : MALE

Clinical sign	Group Name	Admini	istration \	Week-day _				-		· ····					
		70-7	71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7
EXOPIITHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	1	1	1	1	2	2	2	2	2	2	2	2	2	2
	1000 ppm	0	0	1	1	1	1	1	1	1	1	1	1	I	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
YE OPACITY	Control	0	0	0	0	0	0	0	. 0	0	0	0	0	0	0
	mag 003	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	1	1	l	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	1	1	I	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
XTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	1000 ррт	i	1	0	0	0	0	0	0	0	0	0	0	2	2
	2000 ppm	0	ō	0	0	1	1	1	0	0	0	0	0	0	0
NTERNAL MASS	Control	2	2	2	1	1	1	1	1	6	6	5	5	7	2
	500 ppm	0	0	1	1	1	1	1	0	0	0	0	0	1	1
	1000 ppm	4	4	4	4	3	3	3	3	3	3	3	3	3	3
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
i. Eyb	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

SEX : MALE

linical sign	Group Name		stration W	eek-day <u> </u>											27.
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-1
						•									
XOPIITHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	2	2	2	2	2	2	2	2	2	1	1	1	1	1
	1000 ppm	i	i	1	1	1	1	1	I	i	1	i	1	1	i
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
E OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
XTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	500 բբա	0	1	0	0	0	0	0	2	1	I	1	0	0	(
	1000 ррт	2	2	2	2	2	2	2	2	2	2	2	2	2	:
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
NTERNAL MASS	Control	2	2	2	2	2	2	4	4	4	4	5	4	4	4
	500 ppm	1	1	1	1	1	1	1	1	1	1	1	3	3	
	1000 ppm	4	4	4	4	4	4	5	5	5	5	6	6	6	;
	2000 ppm	1	2	1	1	1	2	1	2	1	1	3	3	3	:
I. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	!
i. EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	
	1000 ppm	1	I	1	1	i	1	l	1	1	1	1	1	1	
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	
I. MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

CIEV + HALD

linical sign	Group Name	MORRELL	istration '	чеек∵αау _					
		98-7	99-7	100-7	101-7	102-7	103-7	104-7	
XOPIITIIALMOS	Control	0	0	0	0	0	0	0	
VOLILLIUM	500 ppm	1	1	1	1	1	1	1	
	1000 ppm	i	1	1	1	Ī	I	i	
	2000 ppm	0	0	0	0	Ô	0	0	
	Door pp	•	•	•	_	_	-	_	
EYE OPACITY	Control	0	0	0	0	0	0	0	
	500 ppm	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	
CATARACT	Control	0	0	0	0	0	0	0	
mmaioi	500 ppm	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm 2000 ppm	0	0	0	0	0	0	0	
	2000 ppm	U	U	U	U	U	U	U	
EXTERNAL MASS	Control	1	0	1	1	1	0	0	
	500 ppm	0	0	0	0	0	0	0	
	1000 ppm	2	2	2	1	1	1	i	
	2000 ppm	0	0	0	0	1	2	2	
INTERNAL MASS	Control	3	3	3	4	5	6	6	
	500 ppm	4	4	6	6	5	7	6	
	1000 ppm	5	5	6	6	8	11	11	
	2000 ppm	2	2	3	5	5	4	4	
M. NOSE	C11	0	0	0	0	0	0	0	
A. NOSE	Control	0	0	0	0 0	0		0	
	500 ppm	0					0		
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	
M. EYE	Control	0	0	0	0	0	0	0	
	500 ppm	0	0	0	0	0	0	0	
	1000 ppm	1	1	1	1	1	1	1	
	2000 ppm	0	0	0	0	0	0	0	
M. MANDIBULAR	Control	0	0	0	0	0	0	0	
" ME TO TOOLING	500 ppm	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE

Clinical sign Group Name Administration Week-day 9-7 10-7 11-7 12-7 13-7 14-7 7-7 8-7 4-7 5-7 6-7 1-7 2-7 3-7 M. EAR Control 500 ppm 1000 ppm 2000 ppm M. NECK Control 500 ppm 1000 ppm 2000 ppm Control M. BREAST 500 ppm 1000 ppm 2000 ppm M. ABDOMEN Control 500 ppm 1000 ppm 2000 ppm M. HINDLIMB Control 500 ppm 1000 ppm 2000 ppm M. GENITALIA Control 500 ppm 1000 ppm 2000 ppm ANEMIA Control 500 ppm 1000 ppm

PAGE: 17

CRUSTA

2000 ppm

Control

500 ppm

1000 ppm

2000 ppm

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STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE

PAGE: 18 Clinical sign Group Name Administration Week-day

linical sign	Group Name	Admini	stration W	eek-day _											
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
EAD	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. EAR	500 ppm	0	0	0	0	0	0	0	Ö	0	0	0	Ö	Ö	Ö
		0	0	0	0	0	0	0	0	0	0	0	Ö	Ö	Ö
	1000 ppm	-	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	U	U	U	Ū	U	· ·	Ü	U	U	v	v	Ū	Ū
. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	ŏ	ő	Ö	ŏ	Ŏ	ō	Ö	Ö	0	0	Ō	0	Ŏ	0
	1000 ppm	0	0	0	0	0	ō	0	ō	0	0	0	0	0	0
	2000 ppm	0	Ö	0	Ō	0	ō	Ō	Ŏ	Ö	Ō	0	ō	0	0

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STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE

linical sign	Group Name	Admini	stration W	eek-day _										40.77	41.2
•		29-7	30-7	31-7	32-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7
. ear	Control	0	0	0	0	0	0	0	0	0	0	0	0	. 0	0
. Dia	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	U	U
M. BREAST	Control	0	0	0	0	0	0	0	0	0 0	0 0	0	0	0 0	0
	500 ppm	0	0	0	0	0	0	0	0		0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0 0	0 0	0 0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	U	U	U	U	U	U	U	
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0 0	0 0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	U	U	U	U	U	U
M. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0 0	0 0	0	0 0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0 0	0 0	0 0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	U	U	U	U	Ū	U	· ·		
M. GENITALIA	Control	0	0	0	0 0	0 0	0 0	0 0	0	0	0 0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	o o	0	Ö
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	υ	U	U	U	U		U	Ü	U	v			
ANEMIA	Control	0	0	0	0	0	0 0	0 0	0	0 0	0	0	0	0 0	0
	500 ppm	0	0	0 0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	U	U	U	U	U	v	v	Ū	v			-		_
CRUSTA	Control	0	0	0 0	0	0	0	0 0	0	0	0	0	0	0 0	0
	500 ppm	0 0	0 0	0	0	0	0	0	0	0	0	0	0	0	ď
	1000 ppm		0	0	0	0	0	0	0	0	0	0	ō	0	ì
	2000 ppm	0	U	U	U	U	U	Ų	U	U	v	J	J	v	

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-day											
		42-7	43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-1
										_	_				
M. EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	mqq 0001	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
M. GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	mqq 003	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	mqq 0001	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
CRUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name		stration We	ek-day						~	or 7	- CC 7	67-7	68-7	69-7
		56-7	57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	01-1	00-1	
		^	^	0	0	0	0	0	0	0	0	0	0	0	0
i. ear	Control	0	0	0	0	0	0	0	0	0	Ö	Ö	0	0	0
	500 ppm		0	0	0	0	0	i	ı	1	i	1	1	1	1
	1000 ppm	0 0	0	0	0	0	0	0	0	ō	0	0	0	0	0
	2000 ppm	U	U	U	Ū	v	v	Ü	v	•					
. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ррш	0	0	0	0	0	0	0	0	0	0	0	U	U	U
A. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
n walder i	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	Ō	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I. ADDOMEN	500 բթա	0	0	ő	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	Ö	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	ŏ	ŏ	Ö	Ō	0	0	0	0	0	0	0	0	0
			•	•	0	0	0	0	0	0	0	0	0	0	0
M. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	Ö	Ö	Ŏ
	500 ppm	0	0	0	0	0	0	0	0	0	0	ő	0	Ö	ō
	1000 ppm	0	0	0	0	0	0	0	0	0	Ö	Ö	0	0	0
	2000 ppm	0	U	U	U	v	V	J	•	·	•	•	-	-	-
M. GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	U	·
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(
CRUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	
·····	500 բբա	Ō	ō	0	0	0	0	0	0	0	0	0	0	0	1
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1

500 ppm

1000 ppm

2000 ppm

Control

500 ppm

1000 ppm

2000 ppm

Control

500 ppm

1000 ppm

2000 ppm

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE: A1 104

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-dav											
Silnical Sign	Oroup Name	70-7	71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7
A. EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	1	1	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
A. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
H. HECK	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	Õ	0	0	Ŏ	Ö	0	0	0	0	0	0	0	0
	2000 ppm	0	0	Ô	Ö	Ō	0	0	0	0	0	0	0	0	0
	2000 pp.m	·	•	•	•										
M. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IN TATABLE	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	. 0	0	0	0	0	0	0	0	0
M. GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500			•	•	^	^	Λ	0	Λ.	n	n	0	£ 0	0

PAGE: 22

ANEMIA

CRUSTA

Administration Week-day

Group Name

Control

500 ppm

1000 ppm

2000 ppm

Control

500 ppm

1000 ppm

2000 ppm

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE

Clinical sign

Clinical sign	Group Name	Admini	stration ?	leek-day _											
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
				•	•	^	^	0	0	0	0	n	0	0	0
M. EAR	Control	0	0	0	0	0	0	0		0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	-	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	U	U		· ·	Ū
M. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ррт	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	1	i	1	1	l	1	1	i	1	1	1	1	1	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
mi tupo ombi i	500 ppm	0	0	0	0	0	0	0	1	1	1	1	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	Ō	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	. 0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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ANEM1A

CRUSTA

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admini	stration	Veek-day					
011111111 1/16H	ar ask	98-7	99-7	100-7	101-7	102-7	103-7	104-7	
M. EAR	Control	0	0	0	0	0	0	0	
	500 ppm	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	
M. NECK	Control	0	0	0	0	0	0	0	
m. Hoon	500 ppm	0	0	0	0	0	0	0	
	1000 ppm	0	0	ŏ	0	0	0	0	
	2000 ppm	Ö	0	ŏ	0	0	0	0	
	Zooo ppm	v	v	v	v	v	·	Ţ	
M. BREAST	Control	0	0	0	0	0	0	0	
	500 ppm	0	0	0	0	0	0	0	
	1000 ppm	1	i	1	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	
M. ABDOMEN	Control	0	0	0	0	0	0	0	
M. ADDOMESS	500 ppm	0	0	0	Ö	Ö	0	Ō	
	1000 ppiii mqq 0001		0	0	0	0	ŏ	Ö	
	2000 ppm 2000 ppm	0	0	0	0	0	0	ő	
	2000 ppm	•	•	•	-				
M. HINDLIMB	Control	0	0	1	1	1	0	0	
	500 ppm	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	
M. GENITALIA	Control	1	0	0	0	0	0	0	
m. va. i i i i i i i i i i i i i i i i i i i	500 ppm	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	ő	0	0	0	1	2	2	
ANICHETA	Cant1	٥	0	0	. 0	0	0	0	
ANEMIA	Control	0				0	0	0	
	500 ppm	0	0	0	0				
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	
CRUSTA	Control	0	0	0	0	0	0	0	
	500 բրա	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE

MALE													PAGE :	25
ical sign	Group Name	Administration Week-day	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7	_

Clinical sign	Group Name	Adminis	stration We	eek-day											
orga		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
									_		•	^	•	0	0
ORTICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	•	-	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	U	U
RREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ррт	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TACIIYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	Ò	0	0	0	0	0	0	0
RED URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	. 0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
A STATE OF THE STA	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

BATS 4

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admini	stration W												
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
ORTICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ONTICOBEID	500 ppm	Ö	0	0	0	0	0	0	0	0	0	0	0	0	0
	mqq 0001	Ŏ	ŏ	Ö	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	ō	0	0	0	0	0	0	0	0	0	0	0
RREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NO1SY	Control	0	0	0	0	0	0	0	0	0	0 0	0 0	0	0 0	0
	500 ppm	0	0	0	0	0	0	0	0	0 0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	U	U	U	U	U	
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0 0	0
	500 ppm	0	0	0	0	0	0	0	0	0	-	0	0	0	0
	mqq 0001	0	0	0	0	0	0	0	0	0 0	0 0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	U	U	U	U	v	U
TACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0 0	0 0	0	0 0	0
	500 ppm	0	0	0	0	0	0	0	0	0 0	0	0	0	0	0
	mqq 0001	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	U	U	J	U	U	U
ABNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0 0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	U	U	U	v	U	U	v	-	
RED URINE	Control	0	0	0	0	0	0	0	0 0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0 0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0 0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	U	U	U	U	U	v	v	v	U
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0				0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	U	U	U	U	U	U	J	J	J	3	

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admin:	istration P												
		29-7	30-7	31-7	32-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7
CORMICOLLIC	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TORTICOLLIS	500 ppm	0	0	0	0	0	0	1	1	1	1	1	Ö	Ŏ	0
	1000 pmm	0	0	0	0	0	0	0	0	ō	Ô	0	Ö	Ö	0
	2000 ppm	0	0	0	0	0	0	0	0	0	Õ	0	0	Ö	Ö
	2000 ppiii	U	U	v	v	v	·	·	v	ŭ	·	•	,	_	
RREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	.0
Enormine Report Figure 1014	500 ppm	Ö	Ō	Ö	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	ō	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	ō	Ö	0	0	Ō	0	0	0	0	0	0	0	0	0
FACHYPNEA .	C-ntrol	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IACHITADA	Control 500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ö	ō
	mqq 0001	. 0	0	0	0	0	0	0	0	0	0	Ö	Õ	Ö	ō
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	0	ő
											•			•	^
ABNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	•		
	mqq 0001	0	0	0	0	0	0	0	0	0	0	0	0	0 0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	U	U
RED URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	500 ppm	0	0	0	ō	ō	Ö	0	0	0	0	0	0	0	(
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	(

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE

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nical sign	Group Name	Admini	stration W	eek-day											
		42-7	43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7
mr.cov 1 70		^	•	•	•	٥	•	۸	0	0	٥	0	0	0	0
TICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0		0				0	0		0
	1000 ppm	0	0	0	0	0	0	0	0	0	0 0	0	0	0	0
	2000 ppm	0	0	0	0	0	U	U	U	U	U	U	U	U	U
EGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ISY	Control	0	0	0	0	0	0	0	0	0	0	0	O	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	ō	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	Ô	Ō	0	0	0	0	0	0	0	0	0	0	0	0
NORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	ō	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	ō	0	0	0	Ō	0	0	0	0	0	0	0	0	0
CHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	. 0	0	0
	muu 003	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
D URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	ō	0	Ŏ	0	Ö	ō	0	Ō	ō	0	0	Ö	0
	mqq 0001	0	ō	0	ō	ō	0	0	ō	0	ō	0	0	ō	0
	2000 ppm	0	Ö	0	Ö	ō	0	0	ō	0	ō	Ō	Ō	ō	0
LLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	Ö	Ö	ŏ	Ö	0	0	Ö	ő	Ŏ	Ö	Ŏ	0	ŏ	0
	1000 ppm	Ö	0	ŏ	ŏ	0	0	Ŏ	ō	ů	Ŏ	ŏ	0	ŏ	0
															0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	

(IIAN190)

STUDY NO. : 0372

ANIMAL : MOUSE Cr.j:BDF1

REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admini 56-7	istration W 57-7	eek-day 58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7
					<u></u>										
TORTICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OKITOOLEIS	500 ppm	ŏ	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	ő	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	ō	0	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
RREGULAR BREATHING	Control		0	0	0	0	Ö	Ö	0	0	0	0	1	1	1
	500 ppm	0	0	0	0	0	0	0	0	Ö	0	0	0	0	0
	mqq 0001	0	0	0	0	0	0	0	0	Ö	Ö	0	0	0	0
	2000 ррт	0	υ	U	U	U	U	v	v	·	·				
NOTSA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DIADRADIE RESETUTION	500 ppm	0	Ö	0	0	0	0	0	0	0	0	0	1	1	1
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	Ô	ō	0	0	0	0	0	0	0	0	0	0
TO A CHI IN TO A C	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TACHYPNEA	500 ppm	0	0	0	Ö	0	ŏ	0	0	0	0	0	1	1	1
		0	0	0	0	0	Ö	0	0	0	0	0	0	0	0
	1000 ppm		0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	U	U	U	J	·	v	ŭ	Ţ					
ABNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0 0	0	0	0	C
	500 ppm	0	0	0	0	0	0	0	0	-	0	0	0	0	C
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Č
	2000 ppm	0	0	0	0	0	0	0	0	0	U	U	U	U	,
RED URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	(
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	
IDDLOW UNINE	500 ppm	0	0	0	0	Ö	0	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	
	SOOO BUBI	v	0	J	•		•	•							

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-day 🔔											
		70-7	71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7
ORTICOLLIS	Control	0	0	0	1	1	1	1	1	1	1	1	1	1	1
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	1	1	1	1	1	I	1	1	1	1	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
01SY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	1	1	1	1	1	1	1	1	1	1	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 թբա	1	1	1	1	1	1	1	1	1	1	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	1	1	1	1	1	1	1	1	1	1	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	1	1	1	1	1	1	1	1	1	1	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RED URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	.0	0	0
VELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

MELONI LILE - MI IO

SEX : MALE

Clinical sign	Group Name		istration W									0.1.5	05.7	05.7	67.7
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
CONTROLLIC	01	,	1	1	1	1	2	2	2	2	1	1	1	1	0
CORTICOLLIS	Control 500 ppm	1 0	0	1 0	0	0	0	0	0	0	0	Ô	0	Ô	Ö
		0	0	0	0	0	0	0	Ö	0	0	Ö	Ö	0	Ö
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	o o	0
	2000 ppm	U	U	U	Ū	U	v	v	v	· ·	v	v	ŭ	·	ŭ
RREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	1	2	i	Į	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	2000 ppm	0	0	0	0	1	1	0	0	0	0	0	0	1	0
OISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	Ö	0	Ö	0	0	Ö	Ŏ	0	ō	0	0
	mqq 0001	0	0	0	0	0	ō	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	ō	0	0	0	0	0	0	0	0	0	0
			•		•		^		•	^		•	,	1	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	1	2	1	1	
	500 թբա	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	2000 ppm	0	0	0	0	1	1	0	0	0	0	0	0	1	0
TACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TENOTE IN THE PROPERTY OF THE	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	ŏ	Õ	0	ō	0	0	0	0	0	0	0	0	0
RED URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NED ONTHE	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0 0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	U	U	U	U	U	U	U	U	U	U	U	U	U
YELLOW URINE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

CLINICAL OBSERVATION (SUMMARY) STUDY NO. : 0372 ALL ANIMALS

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

Clinical sign	Group Name	Admini	stration	Week-dav					
		98-7	99-7	100-7	101-7	102-7	103-7	104-7	
TORTICOLLIS	Control	0	0	0	0	0	0	0	
ONTTOUBSIS	500 ppm	ŏ	0	ő	0	0	ő	0	•
	1000 ppm	ő	0	ő	0	ő	Ö	0	
	2000 ppm	0	ō	ō	. 0	0	0	0	
TRREGULAR BREATHING	Control	1	0	0	0	1	1	0	
	500 ppm	0	0	0	1	0	1	0	
	1000 ppm	1	1	2	0	0	0	0	
	2000 ррш	0	0	0	0	0	0	0	
NOISY	Control	0	0	0	0	0	0	0	
	500 ppm	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	
ABNORMAL RESPIRATION	Control	1	0	0	0	1	1	0	
	500 ppm	0	0	0	1	0	1	0	
	1000 ppm	1	1	2	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	
TACHYPNEA	Control	0	0	0	0	0	0	0	
	500 ppm	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	
ABNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	
	500 ppm	0	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	
RED URINE	Control	0	0	0	0	0	0	0	
	500 ppm	1	0	0	0	0	0	0	
	1000 ppm	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	
YELLOW URINE	Control	0	0	0	0	0	0	0	
	500 ppm	0	0	0	0	0	0	0	
	1000 ppm 2000 ppm	0	0	0	0 0	0 1	0	0	

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

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Clinical sign	Group Name	Admini	stration We	eek-day											
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	I	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OLIGO STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	mqq 003	0	0	0	0	2	0	2	0	0	0	0	0	0	0
	1000 ррш	0	0	0	0	0	0	2	0	1	0	0	0	0	0
	2000 ppm	0	0	2	0	0	0	0	0	0	0	1	1	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NON REMARKABLE	Control	50	49	49	50	49	49	49	49	49	49	50	50	50	50
	500 ppm	50	50	50	50	48	50	48	50	50	50	50	50	50	50
	1000 ppm	50	50	50	50	49	49	47	49	48	49	50	50	50	50
	2000 ppm	50	50	48	50	49	49	48	48	47	48	47	47	48	48

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STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : AI 104

SEX : MALE

linical sign	Group Name	Admini	stration W	eek-day _											
annout orga		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
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SERVED BIOOD	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	ō	0	0	0	0	0	0	0	0	0	0	0	0	0
	Boos pp														
OLIGO-STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10.100-31001.	500 ppm	0	0	Õ	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	i	n	0	Ô	0	0	0	0	0	0	0	0	0	0
	2000 ppm	Ô	Ö	Ö	0	0	0	0	0	0	0	0	0	0	0
	2000 ppin	v	ŭ	•	•	-									
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SODNORMAL TEMP	500 ppm	0	n	ŏ	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	n	0	Ö	0	0	0	0	0	0	0	0	0	0
	2000 ppm	ő	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 (1)	v	Ū	·	•	=									
NON REMARKABLE	Control	50	50	50	50	50	50	50	50	49	49	49	49	49	49
HOM VEWRINGATION	500 ppm	50	50	49	49	49	49	49	49	49	49	49	49	49	49
	1000 ppm	49	49	49	49	49	49	49	49	49	49	49	49	49	49
	2000 ppm	49	49	48	49	49	49	49	49	49	49	49	49	49	49
	2000 ррш	15		10											

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STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

PAGE: 35

Clinical sign	Group Name	Admini	stration W	eek-day											
		29-7	30-7	31-7	32-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	U
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OLIGO-STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	1	1	0	0	0	1	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NON REMARKABLE	Control	49	49	49	50	49	49	49	49	49	49	49	49	49	49
	500 ppm	49	49	49	50	49	48	48	48	48	48	48	48	48	48
	1000 ppm	48	48	48	50	48	48	48	48	48	47	47	47	47	46
	2000 ppm	49	49	49	50	49	49	49	49	49	49	50	49	49	49

(IIAN190)

BAIS 4

STUDY NO. : 0372

CLINICAL OBSERVATION (SUMMARY)

 \sim

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 104

ALL ANIMALS

SEX : MALE PAGE: 36

Clinical sign	Group Name	Admini	stration W	eek-day											
		42-7	43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I,IGO-STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0 .	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NON REMARKABLE	Control	49	49	49	49	49	49	49	49	49	49	49	49	49	49
	500 ppm	48	48	48	48	48	48	48	48	48	48	48	48	48	48
	1000 ppm	47	47	47	47	47	47	47	47	47	47	47	47	46	46
	2000 ppm	49	49	49	49	49	49	49	49	49	49	49	49	49	49

(IIAN190) BAIS 1

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0372

PAGE: 37 SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-day _											
,,		56-7	57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	1	0	0	1	0	0	0	1	2	1
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OLIGO-STOOL	Control	0	0	0	0	0	0	0	1	0	0	0	0	0	0
013100 310013	500 ppm	0	0	n	0	1	0	0	2	0	0	1	1	2	1
	1000 ppm	ñ	Ô	0	Ö	ō	0	0	0	0	0	0	0	0	0
	2000 ppm	1	Ŏ	0	0	0	0	0	1	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0 . 1	40	40	40	40	49	49	49	48	49	49	49	49	48	48
NON REMARKABLE	Control	49	49	49	49			49 46	44	46	46	45	45	44	44
	500 ppm	48	48	47	46	45	46						45 45	43	44
	1000 руш	46	46	46	46	45	45	45	45	45	45 49	45	45 49	43 49	49
	2000 ppm	48	49	49	49	49	49	49	48	49	49	49	49	49	49

BAIS 4 (IIAN190)

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

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SEX : MALE

PAGE: 38

Clinical sign	Group Name	Admini	stration W	eek-day											
		70-7	71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7
SMALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	1	0	0	0	0	0	1	1	1	1	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OLIGO-STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	ī	0	0	0	0	0	0	0	1	1	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 թթտ	0	0	1	1	1	1	0	0	1	0	0	0	1	2
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NON REMARKABLE	Control	48	48	48	48	48	48	48	48	43	42	42	42	40	45
	500 ppm	44	44	43	43	42	42	42	42	42	42	42	42	41	41
	1000 ppm	44	44	44	44	45	45	45	45	45	45	45	45	44	44
	2000 ppm	49	49	48	48	48	48	48	48	47	48	48	48	47	46

(IIAN190)

BAIS 4

CLINICAL OBSERVATION (SUMMARY) STUDY NO. : 0372 ALL ANIMALS ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

PAGE: 39 SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-day _											
•	•	84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
SMALL STOOL	Control	0	0	1	1	0	0	0	0	1	3	3	3	1	2
	500 ppm	0	0	0	0	0	0	0	0	1	0	0	1	0	0
	1000 ppm	0	0	1	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	1	2	1	1	2	0	0	0	0	0	1	1	1	0
												_			
OLIGO-STOOL	Control	0	0	1	0	0	0	0	1	1	3	3	2	1	1
	500 ppm	0	0	0	0	0	0	0	0	0	0	0	i	0	0
	1000 ppm	0	0	i	0	0	0	1	1	0	0	0	0	1	0
	2000 ppm	2	3	3	2	3	0	1	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	n	0	0	0	0	0	0	0	0	0	0	0
SUDNURMAL IEMF	500 ppm	0	0	0	0	ő	Ö	Ö	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	ő	Ö	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	U	U	U	v	v	v	·	·	·	•	-		_	
NON REMARKABLE	Control	45	45	44	44	44	44	42	41	41	40	39	39	39	37
	500 ppm	41	40	40	40	40	40	40	38	38	38	38	36	36	35
	1000 ppm	43	43	42	42	42	42	40	40	40	40	39	39	39	39
	2000 ppm	46	45	44	44	43	42	41	41	41	41	38	38	38	38

BAIS 4 (HAN190)

STUDY NO. : 0372

CLINICAL OBSERVATION (SUMMARY)

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 104

ALL ANIMALS

SEX : MALE

PAGE: 40

Clinical sign	Group Name	Admin	stration	Week-day				
	· · · · · · · · · · · · · · · · · · ·	98-7	99-7	100-7	101-7	102-7	103-7	104-7
SMALL STOOL	Control	0	0	0	0	0	0	0
	500 ppm	0	0	0	1	0	0	0
	mqq 0001	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0
OLIGO-STOOL	011	0	•	,	•			•
OU100.2100F	Control	2	i	1	0	2	2	0
	500 ppm	0	0	1	Ţ	2	1	0
	1000 ppm	0	0	1	0	0	0	0
	2000 ppm	0	0	0	0	2	0	1
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0
	500 ppm	0	0	0	1	ō	Ö	Ö
	1000 ppm	0	0	0	ō	0	Õ	Ö
	2000 ppm	0	0	0	0	0	0	0
NON REMARKABLE	Control	36	36	35	34	33	27	30
	500 ppm	34	35	33	33	32	28	30
	1000 ppm	39	38	36	35	33	29	30
	2000 ppm	38	38	37	35	34	32	33
	2000 ppm	30	30	91	33	2.1	34	99

(IIAN190)

BAIS 4

APPENDIX A 2

CLINICAL OBSERVATION: SUMMARY, MOUSE: FEMALE

(2-YEAR STUDY)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0372

PAGE: 41 SEX : FEMALE

Clinical sign	Group Name	Admini	stration We	ek-day											
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
CATU	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EATH	Control 1000 ppm	0	0	0	0	0	0	0	0	0	0	Ö	Ö	0	Ö
	2000 ppm 2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	ő
		0	0	0	0	0	0	0	0	0	0	0	Ô	0	ő
	4000 ppm	U	U	U	U	U	U	U	U	U	U	U	v	U	·
DRIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OCUMOTOR MOVEMENT DECK	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	Ö	0	Ö
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	Ô	0	0
	4000 ppm	0	U	U	U	U	U	U	U	U	U	U	v	U	Ū
UNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	Ō	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TOOMSTION	1000 ppm	Ő	0	Õ	Ö	1	ŏ	0	ŏ	Ŏ	ŏ	Ō	Ö	Ō	Ō
	2000 ppm	0	0	0	0	3	0	0	0	0	0	0	Õ	Ö	ō
		0	0	0	0	0	0	0	0	ő	0	0	0	0	0
	4000 ppm	U	U	U	U	v	v	U	U	v	v	v	v	Ü	J
ROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
XOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
and an annihilation	1000 ppm .	0	Ö	Ö	0	Ō	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	Ö	0	ŏ	Ö	Ö	Õ	Õ	0	0	0	0	0
	4000 ppm	0	0	0	0	ŏ	Ö	Ö	ŏ	0	ō	0	0	Ō	0

STUDY NO. : 0372
ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : FEMALE

linical sign	Group Name	Admini	stration W	eek-day _											
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		4	•		•	•	^	0	٥	0	٥	٥	٥	0	0
EATII	Control	0	0	0	0	0	0	0	0	0 0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0			-	-		0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	-
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DECOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0 '	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
ROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
KOPHTIIALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

CLINICAL OBSERVATION (SUMMARY)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admini	istration V	Veek-day											
		29-7	30-7	31-7	32-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7
	0 . 1	•	•	^	^	•	•	•	^	0	^	^	^	^	0
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OCOMOTOR MOVEMENT DECR	· Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
UNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	Ö	Ö	i	Ö	Ō	Ō	Ö	Ö	Ö	Ö	0	ō
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	ō	0	0	0	0	0	0	0	ō
	4000 ppm	0	ō	0	Ö	Ö	ō	0	o	0	ō	0	0	ő	0
XOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	Õ	Ö	0	Ö	0	ő	0	0	0	Ŏ	Ö	Ö	0	0
	2000 ppm	Ö	Ő	0	0	0	ő	0	0	0	0	0	0	0	0
	4000 ppm	ő	0	0	0	0	Ö	0	0	0	0	0	0	0	0
	1000 ppm	v	v	•	v	v	•	v	v	v	v	v	•	v	U

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

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Clinical sign	Group Name	Admini	stration W	eek-dav											
officer officer	oroup name	42-7	43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7
			•					•	•	•	0	9	9	2	2
DEATH	Control	0	0	0	0	1	1	1	1	1	2	2 1	2 1	1	1
	1000 ppm	0	0	0	0	0	1	1	1	1	1	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0				
	4000 ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
ORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TOO WO TO UNITED THE PROPERTY OF THE PROPERTY	1000 ppm	0	0	0	0	0	0	0	ő	Ö	Ö	Ŏ	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	ő	0	Ö	ŏ	Ŏ	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	U	U	U	U	U	U	U	Ū	U	U	v	v	Ů	Ū
UNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	O	O	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TEOLIGICAL TON	1000 ppm	0	0	1	1	1	0	0	ő	0	Ö	0	Ö	Ō	Ō
	2000 ppm	0	0	Ô	Ô	ō	0	0	Ö	0	0	0	0	0	0
	4000 ppm	0	0	0	0	1	1	0	1	1	1	1	1	ō	ŏ
	mqq ooor	v	٠.	v	v	1		•		1	•	•	•	•	v
ROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	. 1	1	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	1	1	0	0	0	0	0	0 .	0	0
XOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	Ö	Ö	0	0	Ō	0	0	0	0	0	0	0	0	1
	4000 ppm	0	0	ő	Ö	0	ŏ	0	0	Ō	0	0	0	0	ō

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admin	istration W												
		56-7	57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7
ND 4001	Ct1	2	2	2	2	2	2	2	2	2	2	2	2	2	2
DEATH	Control 1000 ppm	1	1	1	1	1	1	1	1	1	2	2	2	2	2
	2000 ppm	i	1	1	1	i	1	ī	1	1	1	1	1	1	1
	4000 ppm	I	1	1	1	1	1	1	2	2	2	2	2	2	2
	4000 ppm	1	1	1	1	1	. *	1		-	J	-			
ORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OCOMOTOR MOVEMENT DECK	1000 ppm	0	0	0	0	0	0	0	Ů	Ŏ	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	Ö	ō	0	0	0	0	0
		0	0	0	0	0	0	Ö	0	ő	o o	0	0	0	0
	4000 ppm	U	U	U	U	U	Ū	v	J		Ü	·	-	•	_
UNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
mulbillo onti	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	ō	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TI ADDOGRAM	0 1	^	0	0	0	0	0	0	0	0	0	0	0	0	1
PILOERECTION	Control	0	0	0	0	0	0	0	0	Ö	0	Ö	Ö	ő	ō
	1000 ppm	0		0	0	0	0	0	0	0	Ö	0	0	0	1
	2000 ppm	0	0				0	0	0	1	1	1	1	1	2
	4000 ppm	0	0	0	0	0	U	U	U	1	1		ı		2
ROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	1	1	1	1	1	1	1	1
WOLLITTURNOO	1000 ppm	0	0	Ö	ő	Ö	Ŏ	0	Ô	ō	0	0	0	0	0
	2000 ppm	0	0	0	Ö	0	ō	Ö	0	ŏ	Ö	Ö	Ō	0	0
	4000 ppm	0	0	0	0	0	Ŏ	0	0	0	ŏ	ō	Ō	0	0
	4000 ppm	U	U	v	U	U	V	v	v	v	•	•	•	•	

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0372

SEX : FEMALE

linical sign	Group Name	Admini	stration W	eek-day											
		70-7	71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7
GATH .	Control	2	2	2	2	2	2	3	3	3	4	6	8	9	9
DAIII	1000 ppm	2	2	2	3	4	4	4	5	5	5	6	6	7	8
	2000 ppm	ے ا	1	2	2	2	3	3	3	4	4	5	5	5	6
		2	2	2	2	3	3	3	3	4	4	4	5	5	5
	4000 ppm	2	2	2	۷	J	J	J	J	4	7	4	J	J	Ü
RIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
COMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
COMOTOR MOVEMENT DECK	1000 ppm	0	0	0	0	0	0	0	. 0	0	0	0	ő	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ő
		0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	U	U	U	U	U	U	U	U	U	Ü	v	v	v	J
NCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 թթա	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Main III on II	1000 ppm	ů.	ō	Ö	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	ő	Ö	ŏ	0	o o	ŏ	0	ō	0	Ö	0	0	0
	4000 ppm	Ö	0	0	0	Ö	Ö	Ō	ō	0	0	0	0	0	0
										4		,	,		
LOERECTION	Control	1	1	1	1	1	2	1	1	1	1	1	1	1	1
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	0
	4000 ppm	1	1	1	1	0	0	0	0	0	1	1	1	2	2
OG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
COPHTHALMOS	Control	1	1	1	1	1	1	1	1	1	0	0	0	0	0
VOI III III III III III III III III III	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ö	0
	2000 ppm 2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	1	1	1
	4000 ppm	U	υ	U	U	U	U	U	U	U	U	U	ı	ī	1

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE: A1 104

STUDY NO. : 0372

SEX : FEMALE

Clinical sign	Group Name		stration W			******									
		84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
	0 . 1		10		.,	11	11		19	10	1.4	1.4	1.4	15	15
EATH	Control	10	10	11	11	11	11	11	13	13	14 13	14 13	14 14	15 14	16
	1000 ppm	8	8	8	9	9	9	10	12	13		13	13	13	14
	2000 ppm	6	7	7	8	10	10	10	11 7	11 8	12 9	9	9	9	9
	4000 ppm	5	5	6	6	7	7	7	f	8	Э	9	9	y	ð
ORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	2000 ppm	0	0	i	1	1	1	1	1	1	1	3	3	3	3
	4000 ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	1
OCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	2	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
UNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
ARALYTIC GAIT	Control	0	0	0	0 -	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ILOERECTION	Control	i	1	1	1	1	1	1	1	1	1	1	1	1	1
	1000 ppm	0	0	0	0	0	0	0	0	1	0	0	0	1	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	2
	4000 ppm	2	2	2	2	2	4	5	5	4	3	2	2	2	6
ROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
XOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1

CLINICAL OBSERVATION (SUMMARY)

ANIMAL : MOUSE Cr.j:BDF1 ALL ANIMALS

REPORT TYPE : A1 104

STUDY NO. : 0372

SBX : FEMALE

Clinical sign	Group Name	Admini	stration 1	Week-day _				
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
					•			
DEATH	Control	15	16	18	19	20	22	24
DEATH	1000 ppm	16	17	17	17	19	20	20
	2000 ppm	14	15	16	17	19	19	19
	4000 ppm	9	10	11	11	13	14	14
	4000 ppiii	5	10	11	11	15	1.7	14
MORIBUND SACRIFICE	Control	0	0	0	0	0	1	2
	1000 ppm	1	1	1	1	1	I	1
	2000 ppm	3	3	3	3	3	3	3
	4000 ppm	1	1	1	2	2	2	2
			_		_	_		
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	1	0
	1000 ppm	0	0	0	0	0	. 0	0
	2000 ppm	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0
nonoizhion i obilion	1000 ppm	0	Ö	0	ő	0	0	Ō
	2000 ppm	1	1	0	0	Ö	0	Ŏ
	4000 ppm	0	0	0	0	0	0	0
	1000 ppm	•	·	·	· ·	·	•	Ť
PARALYTIC GAIT	Control	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	1
	2000 ppm	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0
PILOERECTION	Control	1	1	2	2	2	2	1
11000001101	1000 ppm	Ô	Ô	ő	0	0	0	0
	2000 ppm	2	1	1	0	0	0	0
	4000 ppm	6	6	8	9	8	8	8
	4000 ppm	υ	ō	ō	a	٥	٥	0
FROG BELLY	Control	0	1	1	0	1	2	1
	1000 ppm	0	0	0	1	0	0	0
	2000 ppm	0	0	1	0	0	0	0
	4000 ppm	0	0	0	0	2	2	3
EXOPIITIIALMOS	Control	0	0	0	0	0	0	0
EVOI IIIINTEMOS	1000 ppm	0	0	0	0	0	0	0
			0					0
	2000 ppm 4000 ppm	0 1	1	0 1	0 1	0	0 0	0
			1	1	1	f1	f)	f)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0372

PAGE: 49 SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-day											
VIIIIVIII VIGI		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
EVEDNAL HACC	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	ő	0
	1000 ppm	0	-					0	0	ő	0	0	o o	Ö	0
	2000 ppm	0	0	0	0	0	0	0		0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	U	U	0	U	U	U	U	U	U
NTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ррт	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 рри	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I. ORAL CAVITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	Ö	Ō	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-day											
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		•		•	•	^	٥	0	0	٥	0	0	0	0	0
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0				
	2000 ppm	0	0	0	0	0	. 0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	U	U	U
NTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. ORAL CAVITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	• •														

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-day											
		29-7	30-7	31-7	32-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7
				•	•		•		^	^	0	0	0	0	0
XTERNAL MASS	Control	0	0	0	0	0	0	0	0	0 0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0		0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0					0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	U
NTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	1	1	1	0	1	1	1	1	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	1	1	1	1	1	1
1. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
i. Eye	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ррт	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ORAL CAVITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1. PERI EAR	Control	0	0	0	0	0	0	0	0	0	. 0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0372

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-dav											
		42-7	43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7
						•	•	•	•				•	•	•
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	1	1	1	1	1	1
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	1	1	1	1	1	1	2	2	1	1	1	1
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	2
	4000 ppm	1	1	1	1	1	1	0	0	0	0	1	1	1	1
A. NOSE	Control	0	0	0	0	0	0	0	0	1	1	1	1	1	1
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ı. eye	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 рри	Ö	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ORAL CAVITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	. 0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	Ö	0	Ō	0	Ö	0	0	Ō	0	0	0	0	0
	4000 ppm	ō	Ö	ō	Ō	Ō	0	0	0	0	0	0	0	0	0
M. FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	ŏ	0	Ŏ	0	0	0	0	Ō	Õ	0	Ō	Ō	0
	4000 ppm	0	Ö	0	ō	0	o	ő	ő	0	o	0	o o	ō	0
M. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	ő	0	ő	0	ō	Ö	Ö	Ö	ŏ	Ö	Ö	Õ	Ö
	2000 ppm	Ö	0	ő	ő	0	0	0	0	ő	ő	Ö	Ö	0	ő
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	add odd	U	U	U	U	U	U	U	U	U	U	U	U	U	

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-day											
		56-7	57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-1
EXTERNAL MASS	Control	1	1	1	1	2	2	2	2	2	2	2	2	2	2
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	1	1	l	1	1
NTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	2	3	3	3	3	3	3	3	5	4	4	5	5	6
	2000 ppm	1	2	2	2	2	2	2	2	2	2	3	3	3	4
	4000 ppm	1	1	1	0	1	1	2	1	1	1	1	1	1	4
. NOSE	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORAL CAVITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ррш	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	C
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-day											
777777007 0780		70-7	71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7
EXTERNAL MASS	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
WIRMAN WASS	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	Ō	0	0	0	0	0	0	0	0	0
	4000 ppm	1	1	1	2	2	2	2	2	2	2	2	2	2	2
NTERNAL MASS	Control	1	2	2	3	3	3	1	2	2	3	1	l	0	0
	1000 ppm	6	6	7	8	8	9	9	8	8	9	9	10	8	7
	2000 ppm	4	4	4	7	7	8	8	9	8	9	9	9	11	11
	4000 ppm	4	4	5	6	5	5	5	5	4	5	5	4	5	5
. NOSE	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
. 1032	1000 ppm	0	ō	Õ	Ô	ō	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	Ö	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	Ö	0	Õ	Ö	0	0	0	0	0	0	0	0	0	0
	1000 ppin	·	· ·	-											
. EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORAL CAVITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. OIML ONVIII	1000 ppm	Ŏ	ŏ	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	Ö	0	Ö	o o	0	0	0	0	0	0	0	0	0
	4000 ppm	ő	Ö	0	0	Ō	0	0	0	0	0	0	0	0	0
	••														
. PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	Ō	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	ő	Ö	0	ō	0	0	0	0	0	0	0	0	0	0
I. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
II HINDERIND	1000 ppm	0	0	0	0	0	0	0	0	0	0	Ô	0	Ö	0
	2000 ppm		0	0	0	0	0	0	0	0	ő	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	U	U	U	v	v	U	v	V	•	•	•	•	•	~

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0372

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-day											
	·	84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
(MDDM41 14400	6 1	0	0	0	0	9	2	3	3	3	3	3	3	3	3
KTERNAL MASS	Control	2	2	2	2	2 0	3 0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0		-			0	0	0	0	0	1
	2000 ppm	0	0	0	0	0	0	0	0			0	0	0	0
	4000 ppm	2	2	1	1	0	0	0	0	0	0	U	U	U	U
TERNAL MASS	Control	0	0	0	0	0	0	1	2	2	1	1	2	1	1
	1000 ppm	7	7	8	7	7	8	8	8	7	6	8	10	11	9
	2000 ppm	12	11	13	12	10	10	10	9	9	8	11	12	12	12
	4000 ppm	5	5	6	7	8	8	10	10	9	8	9	11	12	12
NOSE	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EYE	Control	0	0	0	0	0	0	0	0	1	i	1	1	1	1
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORAL CAVITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PERI EAR	Control	0	0	0	0	0	1	1	1	1	1	1	1	1	1
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FORLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	. 0	0	0	0

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : FEMALE

Control 1000 ppm 2000 ppm 4000 ppm 2000 ppm 4000 ppm 2000 ppm 4000 ppm 2000 ppm 4000 ppm 2000 ppm	98-7 3 0 1 0	3 0 1 2 3 8 12 13	2 0 1 1 4 9	2 0 1 1	102-7 2 0 1 0	103-7 2 0 1	2 0 1
1000 ppm 2000 ppm 4000 ppm Control 1000 ppm 2000 ppm 4000 ppm Control 1000 ppm	0 1 0 1 9 12 13	0 1 2 3 8 12	0 1 1 4 9	0 1 1	0 1	0 1	0
1000 ppm 2000 ppm 4000 ppm Control 1000 ppm 2000 ppm 4000 ppm Control 1000 ppm	0 1 0 1 9 12 13	0 1 2 3 8 12	0 1 1 4 9	0 1 1	0 1	0 1	0
1000 ppm 2000 ppm 4000 ppm Control 1000 ppm 2000 ppm 4000 ppm Control 1000 ppm	0 1 0 1 9 12 13	0 1 2 3 8 12	0 1 1 4 9	0 1 1	0 1	0 1	0
1000 ppm 2000 ppm 4000 ppm Control 1000 ppm 2000 ppm 4000 ppm Control 1000 ppm	0 1 0 1 9 12 13	0 1 2 3 8 12	0 1 1 4 9	0 1 1	0 1	0 1	0
2000 ppm 4000 ppm Control 1000 ppm 2000 ppm 4000 ppm Control 1000 ppm	1 0 1 9 12 13	1 2 3 8 12	1 1 4 9	1	l	1	
4000 ppm Control 1000 ppm 2000 ppm 4000 ppm Control 1000 ppm	0 1 9 12 13	2 3 8 12	1 4 9	1			
Control 1000 ppm 2000 ppm 4000 ppm Control 1000 ppm	1 9 12 13	3 8 12	4 9		•	0	0
1000 ppm 2000 ppm 4000 ppm Control 1000 ppm	9 12 13	8 12	9	4		v	v
1000 ppm 2000 ppm 4000 ppm Control 1000 ppm	12 13	8 12	9		3	2	2
2000 ppm 4000 ppm Control 1000 ppm	12 13	12		9	8	7	7
4000 ppm Control 1000 ppm	13		11	10	10	13	13
Control 1000 ppm			13	12	13	13	14
1000 ppm	1		~~		~~	~~	~~
	1	1	1	1	1	1	1
	0	0	0	0	0	0	0
avvv ppili	0	0	0	0	0	0	0
4000 ppm	0	0	0	0	0	0	0
••				•			
Control	1	1	1	1	1	1	1
1000 ppm	0	0	0	0	0	0	0
2000 ppm	0	0	0	0	0	0	0
4000 ppm	0	1	1	1	0	0	0
Control 1	0	0	0	0	•	0	
							0
							0
							0
4000 ppm	0	1	0	U	0	0	0
Control	1	1	0	0	0	0	0
							0
							ő
							0
1000 ppm	•	·	v	•	v	•	•
Control	0	0	0	0	0	0	0
1000 ppm	0	0	0	0	0	0	0
	1						0
	0	0	0	0	0	0	Ō
Control	0	0	0	0	0	0	0
1000 ppm	0	0	0	0	0	0	0
2000 ppm	0	1	1	1	1	1	1
4000 ppm	0	0	0	0			_
	2000 ppm 4000 ppm Control 1000 ppm 2000 ppm 4000 ppm 4000 ppm Control 1000 ppm 2000 ppm 4000 ppm Control 1000 ppm 2000 ppm 4000 ppm 2000 ppm 4000 ppm	2000 ppm 0 4000 ppm 0 Control 0 1000 ppm 0 2000 ppm 0 4000 ppm 0 Control 1 1000 ppm 0 2000 ppm 0 Control 0 1000 ppm 0 Control 0 2000 ppm 1 4000 ppm 0	2000 ppm 0 0 1 Control 0 0 0 1 1000 ppm 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	2000 ppm 0 0 0 0 0 4000 ppm 0 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	2000 ppm 0 0 0 0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 1	2000 ppm 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	2000 ррт 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0372

SEX : FEMALE

Clinical sign	Group Name	Admini	stration We	ek-day											
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
amuzmu z	0 1	۰	•	•	•	•	^	^	^	•	0	^	0	0	•
M. GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0			
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CORTICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	ō	ō	ō	0	0	Ō	0	0	0	ō	0
TACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	. 0	0	0	0	0	0	0
	2000 ppm	ŏ	Ŏ	0	Ō	Ō	Ō	0	0	ō	Ō	0	Ō	Ö	0
	4000 ppm	ŏ	0	Ö	Õ	Ö	Ŏ	ő	Ö	ő	Ö	0	ő	Ŏ	0

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0372

SEX : FEMALE

Clinical sign	Group Name	Admin	istration V	leek-day _											
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
				•											
M. GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	ō	Ō	Ö	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NEMTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	Ō	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORTICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
REGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-day				·							
		29-7	30-7	31-7	32-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7
GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
GENTIALIA	1000 ppm	0	0	0	0	0	ů	0	Ö	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	û	0	0
	4000 ppm	v	U	U	U	v	V	U	v	U	v	·	•	·	Ū
VEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DINOMINE	1000 ppm	0	Ö	Ü	0	0	ŏ	0	ŏ	Ö	0	0	0	0	0
	2000 ppm	0	0	Ö	ő	Ö	Ö	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	Ö	Ö	0	Ö	Ō	0	0	0	0	0
	4000 ppin	•	Ū	· ·	Ü	Ü	·	•	·	_	-	_			
ORTICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0151	1000 ppm	Ö	Ŏ	ŏ	ō	Ō	0	Ö	0	Ō	0	0	0	0	0
	2000 ppm	0	0	0	Ö	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	. 0	0	0	0	0
DUOLUMP RESETANTION	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm 4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	v	Ü	v	v	•	٧	v	v	v	•	•	•	v	•
ACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0372

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-day											
		42-7	43-7	447	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7
. GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
L GENITALIA		0	0	0 0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0										-	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	U	U	υ	U
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	Ô	Ö	ő	0	0	ŏ	Ō	Ö	0	Ō	Ö	Ō
	2000 ppm	0	0	0	0	ő	Ö	0	Ö	o O	0	0	Ö	Ö	Ŏ
	4000 ppm	0	0	0	0	0	0	0	0	ő	0	0	Ö	0	0
	4000 ppm	U	U	U	U	U	U	U	U	U	U	v	U	· ·	U
ORTICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10101	1000 ppm	Ö	0	Ö	0	Ö	Ŏ	ŏ	0	0	0	Ö	Ö	0	ő
	2000 ppm	0	0	0	0	0	ő	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	v	v	U	U	U	v	v	v	U	v	v	v	v	U
BNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	Ŏ	0	0	Ö	0	0	Ō	0	Ö	Ō	Ŏ	Ō	Ō	ō
	2000 ppm	0	Ô	0	Ő	0	Ô	0	ů 0	ő	Ö	0	Ö	0	0
	4000 ppm	0	0	Ŏ	0	0	0	0	0	0	ő	0	ő	0	0
	4000 ppm	U	U	v	U	U	v	U	U	v	v	v	v	U	U

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX: FEMALE

Clinical sign	Group Name	Admini	istration W	eek-dav											
		56-7	57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7
CONTALLA	C.,	^	٥	0	0	1	1	1	1	1	1	1	1	1	1
f. GENITALIA	Control	0	0	0	0 0	1 0	0	0	0	1 0	1 0	0	0	0	0
	1000 ppm	0		0		0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	-	0			0	0	0	1	1	1	1	1
	4000 ppm	0	0	0	0	0	0	U	U	U	1	1	1	1	1
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
A CONTRACTOR OF THE PROPERTY O	1000 ppm	0	0	0	0	0	0	Ö	0	Ö	ő	0	Ŏ	Õ	ő
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	ő	ō
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppiii	v	v	v	Ü	v	v	v	v	v	·	v	v	Ů	·
ORTICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10101	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	ő
	2000 ppm	0	0	0	0	0	0	Ö	0	0	0	0	Ŏ	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	mdd oor	U	v	v	v	•	v	U	v	v	v	v	v	v	U
BNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO.: 0372 ANIMAL: MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	leek-day											
·		70-7	71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7
anu	a . 1						,	•	•	,		1	•	1	1
L GENITALIA	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	1	1	1	2	2	2	2	2	2	2	2	2	2	2
VEMIA	Control	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORTICOLLIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	Ö	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	2	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	. 0	0	0
	2000 ppm	ō	0	Õ	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	Ö	0	0	0	ō	0	0	0	0	0	0	0	0	0
DISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	ō	Ö	Ö	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	Ö	ō	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	2	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	ō	ő	Ö	ő	ő	ő	ő	0	ŏ	ō	ő	ō	0
ACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	Ō	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	Ô	ŏ	Ů	0	Ō	Ō	Ö	ō	0	Ō	Ō	0	0	Ō
	4000 ppm	0	Ö	0	0	0	0	0	Ō	0	0	0	0	0	0

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0372

PAGE: 63 SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-day											
	•	84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
. GENITALIA	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
CERTINEIN	1000 ppm	0	0	0	0	0	Ô	Ô	Ô	Ô	0	Ô	ō	0	0
	2000 ppm	0	0	0	0	0	0	Ö	0	0	ů	0	Ö	0	0
	4000 ppm	2	2	1	1	0	0	0	0	0	0	0	0	0	0
	тооо ррш	5		•	•	Ū	·	·	·	· ·	•	•	•	•	
IENTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RTICOLLIS	Control	0	0	0	0	0	0	1	1	1	1	1	1	ı	1
MI TOODDID	1000 ppm	Ŏ	Ö	Ö	Ö	. 0	Ö	0	ô	ō	Ô	Ô	Ô	ō	ō
	2000 ppm	0	0	0	0	ō	Ö	0	0	Ô	Ö	0	Ö	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	o	0	0	0
	1000 ppm	•	•	·	v	·	·	·	•	•	•	•	•	·	·
REGULAR BREATHING	Control	0	0	0	1	1	1	2	1	1	1	1	1	1	2
	1000 ppm	0	0	0	0	0	0	1	0	1	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	1
	4000 ppm	0	0	0	0	1	1	1	. 2	1	1	1	0	0	0
ISY	Control	0	0	0	0	0	1	1	1	1	1	1	1	0	0
2101	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	Ô	0	Ö
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	ő	Ô
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	indit ooor	v	V	v	v	V	V	v	v	v	v	v	•	٠	Ū
BNORMAL RESPIRATION	Control	0	0	0	1	1	1	2	1	1	1	2	2	1	2
	1000 ppm	0	0	0	0	0	0	1	0	1	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	2	0	0	1
	4000 ppm	0	0	0	0	1	1	1	2	1	1	1	0	0	0
CHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	1	1	0	0
	1000 ppm	Ô	ő	Ö	Ö	Ö	Ŏ	Ö	Ö	1	ő	Ō	Ō	ő	ő
	2000 ppm	ő	0	Ŏ	ŏ	Ö	ŏ	Ö	Ö	Ô	Ö	ŏ	Õ	Õ	ő
	4000 ppm	Ö	ő	ő	Ö	Ö	0	0	0	Ô	0	Ő	0	0	0

CLINICAL OBSERVATION (SUMMARY)

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

STUDY NO. : 0372

SEX: FEMALE

Clinical sign	Group Name	Admini	stration	Week-day _				
•	•	98-7	99-7	100-7	101-7	102-7	103-7	104-7
M. GENITALIA	Control	1	1	1	1	1	1	1
	1000 ppm	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0
MUDRITA	1000 ppm	0	0	0	0	ő	0	0
	2000 ppm	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0
	4000 ppm	U	U	U	U	U	U	U
HEMORRHAGE	Control	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0
	2000 ppm	0	0	0	. 0	0	0	0
	4000 ppm	0	0	0	0	0	0	0
monutout to	0-1-1	^	0	0	0	0	0	^
TORTICOLLIS	Control	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	1	1
	2000 ppm	0	0	0	0	0	0	0
	4000 բբա	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	2	1	1	2	3	2	1
	1000 ppm	0	0	0	0	0	0	1
	2000 ppm	2	I	0	0	0	0	0
	4000 ppm	0	0	0	1	1	1	1
NOISY	Control	0	0	0	0	0	0	0
1/0101	1000 ppm	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0
	4000 ppm	U	U	U	U	U	U	U
ABNORMAL RESPIRATION	Control	2	1	1	2	3	3	1
	1000 ppm	0	0	0	0	0	0	1
	2000 ppm	2	1	0	0	0	0	0
	4000 ppm	0	0	0	1	1	1	1
TACIIYPNEA	Control	0	0	0	0	0	0	0
	1000 ppm	Ö	0	0	Ö	0	Ö	0
	2000 ppm	ŏ	Ö	0	Ö	Ö	0	0
	4000 ppm	Ŏ	0	0	Ö	Ŏ	ŏ	0
	rooo bbm	•	•	•	•	•	•	•

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0372

SEX : FEMALE

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linical sign	Group Name	Admini	stration W	eek-day							*				
	·	1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
RADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MADITINGA	1000 ppm	0	0	0	0	0	Ů	0	0	0	0	0	0	0	0
	2000 ppm	ő	0	0	0	Ö	0	0	0	0	ő	0	ŏ	Ö	0
	4000 ppm	o	0	ő	0	0	0	0	0	0	ō	ō	ō	0	0
NORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IGO-STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	3	0	0	0	0	0	0	0	0	0
	2000 ppm	1	0	0	0	7	0	0	0	1	0	0	0	0	0
	4000 ppm	1	0	0	0	1	0	0	0	0	0	0	0	0	0
BNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	. 0	0	0	0	0	0	0	0	0	0	0
N REMARKABLE	Control	50	50	50	50	50	50	50	50	50	50	50	50	50	50
	1000 ppm	50	50	50	50	47	50	50	50	50	50	50	50	50	50
	2000 ppm	49	50	50	50	43	50	50	50	49	50	50	50	50	50
	4000 ppm	49	50	50	50	49	50	50	50	50	50	50	50	50	50

(HAN190) BAIS 4 STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1 CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

REPORT TYPE : A1 104

SEX : FEMALE

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linical sign	Group Name	Admini	stration W	eek-day											
	-	15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
RADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MID II NEA	1000 ppm	ő	0	0	0	Ö	Ö	0	o o	0	0	0	Ō	0	0
	2000 ppm	0	0	0	0	0	Ö	0	0	Ö	o o	Ö	Õ	ō	ō
	4000 ppm	o	ő	ō	ŏ	ō	0	0	Ō	Ō	0	0	Ō	0	0
BNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LIGO-STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	i	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
UBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ON REMARKABLE	Control	50	50	50	50	50	50	50	50	50	50	50	50	50	50
	1000 ppm	50	50	50	50	50	50	50	49	49	49	49	49	49	49
	2000 ppm	50	50	50	50	50	50	50	49	50	50	50	50	50	50
	4000 ppm	50	50	50	50	50	50	50	50	50	49	50	49	49	49

(HAN190)

BAIS 4

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 104

STUDY NO. : 0372

PAGE: 67 SEX : FEMALE

Clinical sign	Group Name	Admini	istration Y	Veek-day _											
		29-7	30-7	31-7	32-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7
BRADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DIAD II RUA	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	ő
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	ő	0	0	0	0	Ö	0	0	0	0
MANUAL PROPERTY SOUR															
BNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	. 0	0	0	0	0
MALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DLIGO-STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	mqq 0001	0	0	0	0	0	0	0	0	0	0	0	0	ō	Ō
	2000 ppm	Ü	0	0	Ö	0	0	Ö	0	ō	ō	ŏ	ő	ŏ	Õ
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NON REMARKABLE	Control	50	50	50	50	50	50	50	50	50	50	50	50	50	50
Albert Hittelber	1000 ppm	49	49	49	50	48	49	49	49	50	50	50	50	50	50
	2000 ppm	50	50	50	50	50	50	50	50	50	50	50	50	50	50
	4000 ppm	50	50	50	50	50	50	50	50	49	49	49	49	49	49

(HAN190) BAIS 4

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : FEMALE

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Clinical sign	Group Name	Admini	stration V	leek-day _											
		42-7	43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7
		•	•	•	•	•	•	•	^	•	•	•	•	^	^
RADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	•	0
	2000 ppm	0	0	0	0	0	0	0	0	0 0	0 0	0	O O	0	0
	4000 ppm	0	0	0	0	U	0	0	0	U	U	U	U	0	0
NORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	Ō	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	1	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0
LIGO-STOOL	Control	0	0	0	0	0	0	0	0	. 0	0	0	0	0	0
200 01002	mqq 0001	Ö	0	Ö	ō	Ō	Ō	0	0	0	0	0	0	0	0
	2000 ppm	0	ō	ī	0	Ō	Ö	0	0	Ō	0	0	Ō	1	1
	4000 ppm	Ō	0	1	Ö	ō	o	Ö	ō	Ö	ō	0	0	ō	ō
JBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	ō	0	Ü	0	Ö	Ū	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ON REMARKABLE	Control	50	50	50	50	49	49	49	49	48	47	47	47	47	47
	1000 ppm	50	50	49	49	48	48	48	48	47	47	48	48	48	48
	2000 ppm	50	50	49	50	50	50	50	50	50	50	50	50	49	48
	4000 ppm	49	49	48	49	49	49	49	48	48	48	48	47	48	48

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STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

SEX : FEMALE

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linical sign	Group Name	Admini	stration %	leek-day _											
		56-7	57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7
RADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AUTPNEA	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	n	0	0
	4000 ppm	U	U	U	U	U	U	U	U	U	Ü	U	U	U	U
NORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	1	1	0	0	0
IGO-STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	1	0	1	1	0	0	0	0	0	0	1	0	0
	4000 ppm	0	0	0	0	0	0	0	0	1	0	0	0	0	0
BNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
N REMARKABLE	Control	47	47	47	47	46	46	45	45	45	45	45	45	45	45
	1000 ppm	47	46	46	46	46	46	46	46	44	44	44	43	43	42
	2000 ppm	48	47	47	47	47	47	47	47	47	47	46	45	46	44
	4000 ppm	48	48	48	49	48	48	47	47	46	44	44	45	45	41

(HAN190)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0372

SEX : FEMALE

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linical sign	Group Name	Admini	istration W	eek-day											
	· 	70-7	71-7	72-7	73-7	74-7	75 - 7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7
RADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IND II NON	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	Ő	0	Ö	0	Ö	0	Ö	0	0	Ö	0	Ö
	4000 ppm	o	ō	0	o	ō	ō	ō	ő	Ö	ō	ō	ō	ō	0
NORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MALL STOOL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	1000 ppm	0	0	0	1	0	0	1	0	1	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	1	0	0	1	1	0	0	0	2	0
IGO-STOOL	Control	0	0	0	0	0	0	0	1	1	2	1	0	0	1
	1000 ppm	0	0	0	1	0	0	1	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	1	1	0	0
BNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0 .	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
N REMARKABLE	Control	44	44	44	43	43	43	43	42	42	41	40	39	39	38
	1000 ppm	42	42	41	39	38	37	37	37	36	36	35	34	35	35
	2000 ppm	45	45	44	41	41	39	39	38	38	37	36	36	34	33
	4000 ppm	42	42	42	40	39	40	40	40	40	39	38	38	36	38

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ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 104

STUDY NO. : 0372

SEX : FEMALE

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Clinical sign	Group Name	Admini	istration W	eek-day											
	-	84-7	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7
BRADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	1	1	1	1	1	1	1	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SMALL STOOL	Control	0	0	0	0	0	1	1	0	0	0	0	0	0	1
	1000 ppm	0	0	0	0	0	0	2	0	1	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	2	0	i	2	I	2	0	3
	4000 ppm	0	0	0	0	1	0	2	2	1	0	0	0	0	1
LIGO-STOOL	Control	0	0	0	0	0	2	2	1	1	1	1	0	0	1
	1000 ppm	0	0	0	0	0	0	1	0	0	0	1	0	0	0
	2000 ppm	0	0	1	0	1	0	i	0	0	0	2	2	1	2
	4000 ppm	0	0	0	0	0	0	0	1	1	0	0	2	2	2
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ION REMARKABLE	Control	38	38	37	37	37	34	32	31	31	31	31	30	31	30
	1000 ppm	35	35	34	34	34	33	31	30	30	30	28	25	24	24
	2000 ppm	32	32	29	29	29	29	29	29	29	28	23	21	21	19
	4000 ppm	38	38	36	35	34	34	31	31	31	31	31	27	26	25

(HAN190) BAIS 4

CLINICAL OBSERVATION (SUMMARY)

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

SEX : FEMALE

PAGE: 72

Clinical sign	Group Name	Admini	stration	Week-day _				
		98-7	99-7	100-7	101-7	102-7	103-7	104-7
BRADYPNEA	Control	0	0	0	0	0	1	0
	1000 ppm	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0
ABNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0
SMALL STOOL	Control	1	0	0	2	1	1	0
	1000 ppm	0	1	0	0	0	0	1
	2000 ppm	2	2	0	1	0	0	0
	4000 ppm	1	1	4	3	2	2	2
OLIGO-STOOL	Control	1	0	1	2	1	2	0
	1000 ppm	0	0	0	0	0	0	2
	2000 ppm	1	1	1	1	1	0	0
	4000 ppm	2	3	3	2	2	2	2
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0
	1000 ppm	0	0	0	0	0	0	0
	2000 ppm	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0
NON REMARKABLE	Control	31	29	25	24	22	21	20
	1000 ppm	24	24	23	22	22	21	20
	2000 ppm	19	18	18	18	16	14	14
	4000 ppm	24	23	20	21	18	18	17

(HAN190)

APPENDIX B 1

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

BODY WEIGHT CHANGES (SUMMARY) ALL ANIMALS

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

Administrati	ion week-day						GE:
0-0	1-7	2–7	3-7	4-7	5-7	6-7	
22.8± 0.8	23.5± 1.0	24.8± 1.1	25.4± 1.2	25.9± 1.3	26.9± 1.6	27.6± 1.7	
22.8± 0.8	23.4± 0.9	24.5± 0.9	25.3± 0.9	26.0± 1.0	26.3± 1.6	27.2± 1.1	
22.8± 0.8	22.9± 0.9**	24.3± 0.9*	24.9± 0.8	25.7± 0.9	26.1± 1.4*	26.7± 1.0*	
22.8± 0.8	22. 2± 1. 1**	23.5± 1.0**	23.8± 1.7 * *	24.9± 1.1**	25.1± 1.6₩	26.2± 1.0**	
*: P ≤ 0.05	** : P < 0.01						
	0-0 22.8± 0.8 22.8± 0.8	22.8 ± 0.8 23.5 ± 1.0 22.8 ± 0.8 23.4 ± 0.9 22.8 ± 0.8 $22.9\pm 0.9**$ 22.8 ± 0.8 $22.2\pm 1.1**$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	0-0 1-7 2-7 3-7 22.8 \pm 0.8 23.5 \pm 1.0 24.8 \pm 1.1 25.4 \pm 1.2 22.8 \pm 0.8 23.4 \pm 0.9 24.5 \pm 0.9 25.3 \pm 0.9 22.8 \pm 0.8 22.9 \pm 0.9** 24.3 \pm 0.9* 24.9 \pm 0.8 22.8 \pm 0.8 22.2 \pm 1.1** 23.5 \pm 1.0** 23.8 \pm 1.7**	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	Administration week-day 1-7 2-7 3-7 4-7 5-7 6-7 22.8± 0.8 23.5± 1.0 24.8± 1.1 25.4± 1.2 25.9± 1.3 26.9± 1.6 27.6± 1.7 22.8± 0.8 23.4± 0.9 24.5± 0.9 25.3± 0.9 26.0± 1.0 26.3± 1.6 27.2± 1.1 22.8± 0.8 22.9± 0.9** 24.3± 0.9* 24.9± 0.8 25.7± 0.9 26.1± 1.4* 26.7± 1.0* 22.8± 0.8 22.2± 1.1** 23.5± 1.0** 23.8± 1.7** 24.9± 1.1** 25.1± 1.6** 26.2± 1.0**

ANIMAL : MOUSE Crj:BDF1
UNIT : g

REPORT TYPE : Al 104

SEX : MALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

oup Name	Administration	week-day					
	7-7	8-7	9-7	10-7	11-7	12-7	13-7
Control	28.2± 1.9	29.6± 2.2	29.9± 2.2	30.8± 2.6	31.1± 2.6	32.0± 2.8	32.7± 2.8
500 ppm	27.5± 1.4	28.9± 1.3	29.2± 1.6	29.5± 1.5	29.9± 1.7	30.9± 1.7	31.3± 1.6
1000 ppm	26.7± 1.7**	28.0± 1.3**	27.8± 1.5**	28.8± 1.4**	29.0± 1.6**	29.6± 1.7**	30.1± 1.7**
2000 руш	26.5± 1.1**	27.3± 1.4**	27.2± 1.3**	28.1± 1.4**	28.0± 1.7**	28.6± 1.9**	28.7± 1.6**
Significant differe	ence; *: P ≤ 0.05	**: P ≤ 0.01		Test of Dunnett			

(HAN260)

ANIMAL : MOUSE Crj:BDF1
UNIT : g

REPORT TYPE : A1 104

SEX : MALE

BODY WEIGHT CHANGES

(SUMMARY)

PAGE: 3

ALL ANIMALS

Group Name	Administration	ı week-day					,,,
	14-7	18-7	22-7	26-7	30-7	34-7	38-7

	14-7	18-7	22-7	26-7	30-7	34-7	38-7
Control	33.7± 2.9	36.2± 3.2	38.5± 3.6	40.8± 3.9	42.9± 4.3	44.4± 4.4	45.7± 4.4
500 ppm	32.3± 1.6	34.0± 1.9*	35.9± 2.2*	37.1± 2.3**	38.3± 2.5**	39.0± 3.1**	39.7± 3.8**
1000 ppm	30.8± 1.9**	32.4± 2.3**	33.6± 2.5 * *	35.1± 2.8**	36.1± 2.9≠	36.5± 3.1**	37.4± 3.2**
2000 րրտ	29.4± 1.8**	30.8± 2.0**	31.8± 2.2**	33.2± 2.5**	33.9± 2.4≉	34.5± 2.6**	35.1± 2.7≠

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

(HAN260) BAIS 4

ANIMAL : MOUSE Crj:BDF1

UNIT : g

REPORT TYPE : A1 104 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 4

up Name	Administration	week-day					
	42-7	46-7	50-7	54-7	58-7	62-7	66-7
Control	46.8± 4.5	47.8± 4.2	48.7± 4.3	49.5± 4.0	49.8± 4.0	50.5± 4.0	51.6± 4.2
500 ppm	41.0± 3.1**	41.9± 3.4**	42.7± 3.6**	43.9± 3.7**	43.4± 3.8++	43.3± 4.1**	45.0± 4.2**
1000 ppm	38.2± 3.2**	38.9± 3.5**	39.5± 3.4**	40.3± 3.6**	40.1± 3.7 **	40.0± 3.9**	41.0± 3.9**
2000 ррш	35.9± 2.9**	36.4± 2.9**	37.2± 3.0**	37.4± 3.2**	37.0± 3.4★	36.7± 3.8**	38.0± 3.5**
Significant differe	ence; *: P ≤ 0.05	**: P ≤ 0.01		Test of Dunnett			

(HAN260)

ANIMAL : MOUSE Crj:BDF1

UNIT : g

REPORT TYPE : A1 104

BODY WEIGHT CHANGES (SUMMARY) ALL ANIMALS

SEX : MALE

up Name	Administration	week-day					
•	70-7	74-7	78-7	82–7	86-7	90-7	94-7
Control	52.1± 4.2	52.0± 5.0	52.1± 5.5	52.6± 5.4	52.4± 6.6	51.6± 7.1	50.5± 8.2
500 ppm	45.1± 4.6**	45.6± 4.8**	45.3± 5.3**	46.0± 4.3**	46.1± 4.7★	44.9± 5.2**	44.6± 5.2*
1000 ppm	41.4± 3.9**	41.5± 4.1**	41.7± 4.2**	41.4± 4.3**	41.1± 4.4**	39.4± 4.8**	39.1± 4.2**
2000 թթա	38.4± 3.7**	37.6± 3.5**	38.1± 3.5**	37.7± 3.7 * *	36.5± 4.1**	35.9± 3.9**	35.7± 3.3**
Significant differe	ence; *: P ≤ 0.05	** : P ≤ 0.01		Test of Dunnett			

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BAIS 4 (HAN260)

ANIMAL : MOUSE Crj:BDF1

UNIT : g

REPORT TYPE : A1 104

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

SEX : MALE

oup Name	Administration	week-day		
	-98-7	102-7	104-7	
Control	51.2± 8.1	51.8± 7.4	52.6± 7.0	
500 ppm	44.1± 5.4*	43.5± 5.8**	44.4± 5.4**	
1000 ppm	38.6± 4.3**	38.5± 4.0**	38.8± 3.9**	
2000 բբա	35.2± 2.9**	34. 2± 2. 8**	34.5± 2.8**	
Significant differe	nce; *: P ≦ 0.05	<pre></pre>	Test of Dunnett	

(HAN260)

BAIS 4

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APPENDIX B 2

BODY WEIGHT CHANGES: SUMMARY, MOUSE: FEMALE

(2-YEAR STUDY)

ANIMAL : MOUSE Crj:BDF1
UNIT : g

REPORT TYPE : A1 104

SEX : FEMALE

BODY WEIGHT CHANGES

(SUMMARY)

ALL ANIMALS

up Name	Administration	week-day			···········		
	0-0	1-7	2–7	3-7	4-7	5-7	6-7
Control	18.9± 0.7	18.7± 1.1	19.9± 0.7	20.5± 0.8	21.2± 0.8	21.6± 0.9	22.2± 1.1
1000 ppm	18.9± 0.7	18.9± 0.9	19.8± 0.9	20.5± 1.0	20.8± 0.8	20.7± 1.7*	22.3± 0.9
2000 ppm	18.9± 0.7	18.3± 0.8	19.3± 0.7**	19.8± 0.7**	20.0± 0.9**	20.0± 1.6**	21.0± 0.9**
4000 ррш	18.9± 0.7	16.3± 1.3**	18.1± 1.1**	19.1± 1.0**	19.3± 1.0**	19.7± 1.2**	20.2± 0.9**
Significant difference		**: P ≤ 0.01		Test of Dunnett			

(HAN260)

BAIS 4

PAGE: 7

ANIMAL : MOUSE Crj:BDF1

UNIT : g

REPORT TYPE : A1 104

SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 8

up Name	Administration	week-day					
	7-7	8-7	9-7	10-7	11-7	12-7	13-7
Control	22.7± 0.9	23.2± 0.9	23.3± 1.1	23.9± 1.3	24.1± 1.3	24.1± 1.2	24.7± 1.4
1000 ppm	22.2± 0.9*	22.4± 0.8**	23.0± 0.9	23.5± 1.0	23. 4± 1. 1*	23.5± 1.0**	23.8± 1.1**
2000 ppm	21.5± 1.0**	21.5± 1.0**	22.2± 1.4**	22.5± 1.4**	22.6± 1.0**	22.8± 1.1**	23.3± 1.1**
4000 թթա	20.6± 0.9**	21.1± 0.9**	21.4± 0.9**	21.8± 1.0**	21.8± 1.0**	22.0± 0.9**	22.3± 1.0≠
				T C. D	·		
Significant differe	ence; *: P ≤ 0.05	** : P ≤ 0.01		Test of Dunnett			

(HAN260)

ANIMAL : MOUSE Crj:BDF1

UNIT : g

REPORT TYPE : A1 104

SEX : FEMALE

BODY WEIGHT CHANGES ALL ANIMALS (SUMMARY)

oup Name	Administration	week-day					
	14-7	18-7	22-7	26-7	30-7	34-7	38-7
Control	24.9± 1.4	26.0± 1.6	27.3± 2.1	28.6± 2.4	29.7± 2.9	30.5± 2.9	31.3± 3.0
1000 ppm	24.0± 1.1*	25.1± 1.1	25.8± 1.2*	26.5± 1.2**	27.1± 1.4**	27.6± 1.5**	28.3± 1.5**
2000 ppm	23.2± 1.2**	24.2± 1.0**	24.7± 1.3**	25.5± 1.5**	25.5± 1.5**	26.1± 1.9**	26.7± 1.9**
4000 ppm	22.4± 0.9**	23.3± 0.9**	23.7± 1.2**	24.4± 1.3**	24.5± 0.9**	24.6± 1.2**	25.1± 1.3**
Significant differe	ence; $*: P \leq 0.05$	**: P ≤ 0.01		Test of Dunnett			

(HAN260)

BAIS 4

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ANIMAL : MOUSE Crj:BDF1

UNIT : g

REPORT TYPE : A1 104

SEX : FEMALE

BODY WEIGHT CHANGES

ALL ANIMALS

 \searrow

PAGE: 10

up Name	Administration	week-day					
	42-7	46-7	50-7	54-7	58-7	62-7	66-7
Control	31.8± 3.5	32.6± 3.5	33.2± 3.5	33.8± 3.7	33.8± 3.8	33.4± 3.5	34.5± 3.5
1000 ppm	28.6± 1.8**	29.6± 2.4*	29.7± 2.2**	30.0± 2.4**	29.7± 2.3**	30.4± 2.5*	31.3± 3.0*
2000 ppm	27.1± 2.1**	26.8± 2.0**	27.6± 2.1**	27.4± 1.9**	27.3± 1.9**	27.2± 2.0**	27.9± 2.2**
4000 ррш	25.3± 1.4**	25.7士 1.5**	25.9± 1.4**	26.0± 1.5**	25.7± 1.4**	25.6± 1.5**	26.1± 1.6**
Significant difference	$*: P \leq 0.05$	** : P ≤ 0.01		Test of Dunnett			

(SUMMARY)

(HAN260)

ANIMAL : MOUSE Crj:BDF1
UNIT : g

REPORT TYPE : A1 104

SEX : FEMALE

BODY WEIGHT CHANGES ALL ANIMALS (SUMMARY)

p Name	Administration						
	70-7	74-7	78-7	82-7	86-7	90-7	94-7
Control	35.1± 3.7	35.5± 3.6	35.4± 3.9	35.7± 3.7	35.6± 3.9	34.7± 4.6	34.2± 4.4
1000 ppm	31.8± 2.9*	32. 1± 3. 1*	32.1± 2.8*	32.5± 3.1*	32.0± 3.3*	31.6± 3.3	31.3± 3.5
2000 ppm	28.3± 2.4**	28.3± 2.5**	28.4± 2.6**	29.1± 3.1**	28.7± 3.7**	28.7± 4.3**	28.6± 4.3**
4000 ppm	25.7± 1.8**	25.5± 1.8**	25.4± 1.8**	24.7± 1.9**	24.0± 2.1**	23.7± 1.7**	23.6± 1.6**
Significant difference	e; *:P≦0.05	** : P ≤ 0.01		Test of Dunnett			

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ANIMAL : MOUSE Crj:BDF1

UNIT : g

REPORT TYPE : AI 104

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

SEX : FEMALE

oup Name	Administration	week-day			
	98-7	102-7	104-7		
Control	34.0± 4.1	33.4 ± 4.6	35.8± 3.1		
		32.0± 4.7	31.5± 4.3*		
1000 ppm	31.3± 3.0	32. U ± 4. ?	31.04.37		
2000 ppm	28.4± 5.1**	28.5± 5.6**	29.3± 5.9**		
	00.511.0	00 5 L 0 0th.	00 04 0 044		
4000 ppm	23.5± 1.9 * *	23.5± 2.2**	23.9± 2.2**		
				·	
Significant differe	ence; *: P ≤ 0.05	* : P ≤ 0.01		Test of Dunnett	
Significant differe	nice, # . 1 \(\frac{1}{2}\) 0.00	· 1 = 0.01		7000 01 200000	

(HAN260)

BAIS 4

PAGE: 12

APPENDIX C 1

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

ANIMAL : MOUSE Crj:BDF1 ALL

UNIT : g

STUDY NO. : 0372

REPORT TYPE: Al 104

SEX : MALE

Administration week-day(effective)_ Group Name 5-7(4) 6-7(4) 7-7(4) 2-7(4) 3-7(4) 4-7(4) 1-7(4) 4.5± 0.9 4.8± 1.0 4.4± 0.9 4.7± 0.9 4.7± 0.8 4.4± 0.7 4.6± 0.8 Control 4.5± 0.7 4.0± 1.2 4.6± 0.9 4.1± 1.0 500 ppm 4.4± 0.8 4.8± 0.8 4.9± 0.8* 3.7± 0.5** 3.8± 0.7** 3.5± 0.6** 3.4± 1.0** 3.8± 0.7** 3.5± 0.9** 1000 ppm 3.4± 0.5** 2.8± 0.6** 2.7± 0.8** 3.2± 0.7** 3.0± 0.6** 2000 ppm 2.3± 0.3** 2.7± 0.6** 2.7生 0.7**

PAGE: 1

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

(HAN260) BAIS 4

ANIMAL : MOUSE Crj:BDF1
UNIT : g

STUDY NO. : 0372

REPORT TYPE : A1 104

SEX : MALE

Group Name	Administration w	eek-day(effective) 9-7(4)	10-7 (4)	11-7(4)	12-7 (4)	13-7(4)	14-7(4)	
Control	4.5± 0.7	4.6± 0.8	4.8± 1.2	4.3± 0.8	4.2± 0.8	4.4± 0.8	4.3± 0.7	
500 ppm	4.3± 0.7	4.2± 0.7	4.5± 1.1	4.0± 0.6	4.1± 0.6	4.1± 0.8	4.1± 0.6	
1000 ppm	3.6± 0.7**	3.4± 0.7**	3.6± 0.8**	3.5± 0.6**	3.4± 0.5**	3.6± 0.6**	3.3± 0.4**	
2000 թթա	3.0± 0.7**	3.2± 0.7**	3.1± 0.7**	2.9± 0.7**	2.9± 0.6**	3.0± 0.6**	3.0± 0.8**	

PAGE: 2

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

BAIS 4 (HAN260)

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1
UNIT : g

REPORT TYPE : A1 104

SEX : MALE

oup Name	Administration 18-7(4)	reek-day(effective) 22-7(4)	26-7 (4)	30-7(4)	34-7 (4)	38-7 (4)	42-7 (4)
Control	3.8± 0.6	3.7± 0.5	3.7± 0.4	3.7± 0.5	4.0± 0.4	4.1± 0.4	4.1± 0.5
500 ppm	3.6± 0.4	3.4± 0.4	3.5± 0.6	3.5± 0.4	3.6± 0.4**	3.9± 0.4	3.7± 0.3**
1000 ppm	3.2± 0.5**	3.0± 0.3**	3.1± 0.4**	3.0± 0.4**	3.2± 0.3**	3.3± 0.4**	3.3± 0.4**
2000 ppm	2.8± 0.4**	2.7± 0.4**	2.7± 0.4**	2.8± 0.4**	2.9± 0.4**	3.0± 0.4**	3.1± 0.4**
Significant differen	nce; *: P ≤ 0.05	o∗: P ≤ 0.01		Test of Dunnett			

BAIS 4

PAGE: 3

(HAN260)

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

STUDY NO. : 0372

SEX : MALE

pup Name	Administration 46-7(4)	week-day(effective) 50-7(4)	54-7 (4)	58-7 (4)	62-7(4)	66-7(4)	70-7 (4)
Control	4.1± 0.4	3.9± 0.5	4.0± 0.4	4.0± 0.4	4.1± 0.4	4.2± 0.5	4.4± 0.6
500 ppm	3.7± 0.3**	3.7± 0.3*	3.6± 0.3**	3.9± 0.7	3.4± 0.9**	3.7± 0.5**	3.9± 0.5**
1000 ppm	3.4± 0.4**	3.3± 0.4**	3.3± 0.3**	3.5± 0.5**	3.4± 0.7★★	3.5± 0.4**	3.6± 0.4**
2000 ppm	3.2± 0.4**	3.0± 0.4**	3.1± 0.4**	3.1生 0.4**	3.1± 0.7★	3.4± 0.4**	3.5± 0.5**
Significant differen	nce; *: P ≤ 0.05 *	*: P ≤ 0.01		Test of Dunnett			

PAGE: 4

BAIS 4 (HAN260)

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

UNIT : g

REPORT TYPE : AI 104 SEX : MALE

p Name	Administration	week-day(effective)				0.4 (14)	00.7(4)
·	74-7(4)	78-7 (4)	82-7 (4)	86-7 (4)	90-7 (4)	94-7 (4)	98-7 (4)
Control	4.4± 0.7	4.5± 0.8	4.6± 0.7	4.4± 0.8	4.5± 0.9	4.2± 1.2	4.7± 0.9
500 ppm	3.8± 0.6**	4.0± 0.5*	4.0± 0.4**	3.9± 0.7**	4.2± 0.4	4.0± 0.4	4.0± 0.4**
1000 ppm	3.6± 0.4**	3.7± 0.5**	3.7± 0.5**	3.6± 0.7**	3.9± 0.7★★	3.9± 0.5*	3.9± 0.6**
2000 ррт	3.4± 0.6**	3.4± 0.5**	3.5± 0.6**	3.3± 0.8**	3.6± 0.9★★	3.8± 0.4**	3.9± 0.6**
Significant difference ;	*: P ≤ 0.05	** : P ≤ 0.01		Test of Dunnett			

(HAN260)

BAIS 4

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STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

UNIT : g

REPORT TYPE : A1 104

SEX : MALE

oup Name	Administration 102-7(4)	week-day(effective) 104-7(4)		
Control	4.8± 0.9	4.6± 0.7		
500 ppm	4.0± 0.6**	4.0± 0.5**		
1000 ppm	4.1± 0.6**	4.0± 0.6**		
2000 րբա	4.0± 0.9**	4.1± 1.0**		
Significant differen	nce; *: P ≤ 0.05	** : P ≤ 0.01	Test of Dunnett	

(HAN260)

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APPENDIX C 2

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

WATER CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1
UNIT : g

REPORT TYPE : A1 104

SEX : FEMALE

ıp Name	Administration 1-7(4)	week-day(effective) 2-7(4)	3-7(4)	4-7 (4)	5-7(4)	6-7(4)	7-7(4)
Control	4.2± 0.7	4.4± 0.5	4.2± 0.4	4.3± 0.4	4.2± 0.4	4.4± 0.5	4.2± 0.4
1000 ppm	3.3± 0.3**	3.3± 0.3**	3.3± 0.3**	3.2± 0.3**	3.1± 0.9**	3.5± 0.5**	3.4± 0.5**
2000 ppm	2.2± 0.3**	2.4± 0.6**	2.3± 0.3**	2.4± 0.4**	2.3± 0.9★	2.7± 0.4**	2.6± 0.4**
4000 ррт	1.6± 0.3**	1.8± 0.2**	1.8± 0.2**	1.9± 0.3**	1.9± 0.3**	2.1± 0.4**	2.0± 0.2**
Significant difference	; *:P≦0.05 >	b*: P ≤ 0.01		Test of Dunnett			

(HAN260)

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STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

UNIT : g

REPORT TYPE : A1 104

SEX : FEMALE

oup Name	Administration 8-7(4)	week-day(effective) 9-7(4)	10-7 (4)	11-7(4)	12-7(4)	13-7(4)	14-7(4)
Control	4.3± 0.4	4.3± 0.4	4.2± 0.4	4.2± 0.4	4.3± 0.4	4.3± 0.5	4.3± 0.5
1000 ppm	3.5± 0.4**	3.6± 0.6≯*	3.5± 0.6**	3.5± 0.3**	3.5± 0.3**	3.8± 0.7*	3.6± 0.7**
2000 ppm	2.6± 0.4**	2.7± 0.5**	2.7生 0.5**	2.7± 0.3**	2.7± 0.3**	2.9± 0.8**	3.0± 0.7**
4000 ррт	2.0± 0.2**	2.1± 0.3**	2.0± 0.6**	2.2± 0.3**	2.2± 0.2**	2.3± 0.5**	2.2± 0.4**
Significant differen	ce; *: P ≦ 0.05	+*: P ≤ 0.01		Test of Dunnett			

BAIS 4

PAGE: 8

(HAN260)

WATER CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

UNIT : g

REPORT TYPE : Al 104

SEX : FEMALE

up Name	Administration 18-7(4)	week-day(effective) 22-7(4)	26-7 (4)	30-7(4)	34-7 (4)	38-7(4)	42-7(4)
Control	4.1± 0.7	4.1± 0.4	4.0± 0.5	4.0± 0.5	4.0± 0.5	3.9± 0.5	3.9± 0.6
1000 ppm	3.4± 0.4**	3.3± 0.5**	3.1± 0.5**	3.2± 0.9**	3.2± 0.7★★	3.2± 0.7**	3.2± 0.9**
2000 ppm	2.7± 0.3**	2.7± 0.4**	2.6± 0.4**	2.7± 0.5**	2.8± 0.5**	2.6± 0.4**	2.6± 0.4**
4000 ppm	2.2± 0.2**	2.0± 0.2**	2.0± 0.3**	2.2± 0.3**	2.2± 0.2**	2.2± 0.3**	2.2± 0.3**
Significant difference	; *: P ≤ 0.05	**: P ≤ 0.01		Test of Dunnett			

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(HAN260) BAIS 4

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

UNIT : g
REPORT TYPE : A1 104

SEX : FEMALE

roup Name	Administration 46-7(4)	week-day(effective) 50-7(4)	54-7 (4)	58-7 (4)	62-7 (4)	66-7 (4)	70-7 (4)
Control	4.0± 0.6	4.0± 0.6	3.9± 0.5	3.8± 0.8	3.9± 0.5	3.9± 0.5	3.7± 0.6
1000 ppm	3.1± 0.4**	3.2± 0.6**	3.0± 0.5**	3.1± 0.5**	3.0± 0.4**	3.0± 0.4**	3.0± 0.3**
2000 ррт	2.7± 0.4**	2.7± 0.4**	2.7± 0.3**	2.6± 0.4**	2.6± 0.4**	2.8± 0.6**	2.7± 0.4**
4000 ррт	2.3± 0.3**	2.3± 0.3**	2.2± 0.2**	2.2± 0.3**	2.3± 0.3**	2.4± 0.3**	2.3± 0.4**
						· · · · · · · · · · · · · · · · · · ·	
Significant differen	nce; *: P ≤ 0.05 *	* : P ≤ 0.01		Test of Dunnett			

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BAIS 4 (HAN260)

WATER CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

UNIT : g

REPORT TYPE : A1 104

SEX : FEMALE

Administration week-day(effective)_ Group Name 78-7(4) 86-7(4) 90-7(4) 94-7(4) 98-7(4)82-7(4) 74-7(4) 3.9 ± 0.9 4.0± 1.0 4.1± 1.0 4.2± 1.1 4.1± 0.8 Control 3.9 ± 0.7 3.9 ± 0.7 3.1± 0.5** 3.1± 0.6** 3.5± 0.8** 3.3 ± 0.6** 1000 ppm 3.0生 0.4** 3.1± 0.5** 3.2± 0.4** 3.5± 0.8** 3.7± 0.9* 2.9± 0.6** 3.1± 0.7** 2.7± 0.6** 2.8± 0.6** 3.0± 0.6** 2000 ppm 4.0± 0.5 3.7± 0.6 2.5± 0.4** 2.8± 0.6** 3.1± 0.5** 3.3± 0.5** 3.4± 0.6** 4000 ppm Significant difference; $*: P \leq 0.05$ **: $P \leq 0.01$ Test of Dunnett

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(HAN260) BAIS 4

ANIMAL : MOUSE Crj:BDF1

UNIT : g

STUDY NO. : 0372

REPORT TYPE : Al 104

SEX : FEMALE

Group Name	Administration w 102-7(4)	reek-day(effective) 104-7(4)		
Control	4.1± 1.1	4.3± 0.7		
1000 ppm	3.5± 0.9	3.3± 0.9**		
2000 ppm	3.8± 0.8	4.1± 0.9		
4000 ppm	3.8± 0.8	3.8± 0.6		

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

(HAN260) BATS 4

APPENDIX D 1

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

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

ANIMAL : MOUSE Cr.j:BDF1

STUDY NO. : 0372 ANIMAL : MOUSE UNIT : g

REPORT TYPE : A1 104

SEX: MALE

oup Name	Administration 1-7(7)	week-day(effective) 2-7(7)	3–7 (7)	4–7 (7)	5-7(7)	6-7 (7)	7-7 (7)
Control	3.7± 0.3	3.9± 0.4	3.9± 0.3	4.0± 0.4	4.0± 0.4	4.1± 0.4	4.1± 0.4
500 ppm	3.6± 0.3	3.8± 0.3	3.9± 0.3	4.0± 0.3	3.9± 0.4	4.1± 0.3	4.0± 0.4
1000 ppm	3.6± 0.2*	3.8± 0.2	3.9± 0.3	3.9± 0.3	3.9± 0.4	3.9± 0.3	3.9± 0.4*
2000 руш	3.4± 0.3**	3.7± 0.2	3.7± 0.3**	3.8± 0.4	3.8± 0.3*	4.0± 0.4	4.1± 0.4
Significant difference	; *: P ≤ 0.05 *	* : P ≤ 0.01		Test of Dunnett			

PAGE: 1

(HAN260) BAIS 4

ANIMAL : MOUSE Crj:BDF1

UNIT : g REPORT TYPE : A1 104

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE: 2

roup Name	Administration 8-7(7)	week-day(effective) 9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	14-7(7)
Control	4.2± 0.4	4.2± 0.4	4.3± 0.4	4.2± 0.4	4.3± 0.4	4.2± 0.3	4.4± 0.3
500 ppm	4.1± 0.4	4.0± 0.3	4.1± 0.3*	4.3± 0.5	4.3± 0.3	4.1± 0.3	4.3± 0.2
1000 ppm	4.1± 0.5	3.9± 0.4**	4.1± 0.4*	4.1± 0.4	4.2± 0.4	4.0± 0.4**	4.2± 0.4**
2000 ррт	4.0± 0.5	4.0± 0.4	4.1± 0.4*	4.1± 0.4	4.1± 0.4	4.0± 0.3**	4.1± 0.3**

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

Test of Dunnett

(HAN260)

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

UNIT : g

REPORT TYPE : A1 104

SEX : MALE

p Name	18-7 (7)	week-day(effective) 22-7(7)	26-7(7)	30-7(7)	34-7 (7)	38-7(7)	42-7(7)
Control	4.4± 0.4	4.5± 0.3	4.5± 0.3	4.7± 0.4	4.9± 0.4	5.0± 0.3	4.9± 0.4
500 ppm	4.3± 0.3	4.2± 0.3**	4.3± 0.3**	4.3± 0.3**	4.6± 0.4≠	4.7± 0.4**	4.6± 0.3**
1000 ppm	4.2± 0.3**	4.2± 0.4**	4.2± 0.3**	4.2± 0.3**	4.5± 0.4**	4.6± 0.4**	4.6± 0.4**
2000 ррт	4.1± 0.3**	4.1± 0.3**	4.0± 0.3**	3.9± 0.4**	4.3± 0.3**	4.3± 0.3**	4.4± 0.3**
Significant difference	· * · P < 0.05	lo*: P ≤ 0.01		Test of Dunnett			

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(HAN260)

ANIMAL : MOUSE Crj:BDF1
UNIT : g

REPORT TYPE : A1 104

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE: 4

oup Name	Administration	week-day(effective)					
	46-7 (7)	50-7 (7)	54-7 (7)	58-7 (7)	62-7 (7)	66–7 (7)	70-7 (7)
Control	5.0± 0.3	4.9± 0.5	5.0± 0.3	4.7± 0.3	4.6± 0.4	5.0± 0.3	5.1± 0.4
500 ppm	4.6± 0.3**	4.8± 0.3	4.6± 0.3**	4.3± 0.3**	3.9± 0.5**	4.6± 0.4**	4.8± 0.4**
1000 ppm	4.5± 0.4**	4.5± 0.4**	4.5± 0.4**	4.2± 0.4**	4.2± 0.3**	4.5± 0.5**	4.7± 0.4**
2000 թթm	4.3± 0.3**	4.5± 0.3**	4.3± 0.3**	4.0± 0.3**	4.0± 0.4**	4.4± 0.3**	4.5± 0.4**
Significant differen	nce; *: P ≤ 0.05 ×	o*: P ≤ 0.01	•	Test of Dunnett			

(HAN260)

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

UNIT : g

REPORT TYPE : A1 104

SEX : MALE

Administration week-day(effective)_ Group Name 78-7(7) 82-7(7) 86-7(7) 90-7(7) 94-7(7) 98-7(7) 74-7(7) Control 5.1 ± 0.3 5.1 ± 0.4 5.2 ± 0.4 4.9 ± 0.8 5.1± 1.0 5.0 ± 0.8 4.9± 0.6 500 ppm 4.7± 0.6** 4.6± 0.5** 4.8± 0.3** 4.7± 0.3* 4.8± 0.4* 4.6± 0.3** 4.5 ± 0.4** 4.6± 0.5** 1000 ppm 4.8± 0.5** 4.6± 0.5** 4.7± 0.5** 4.5± 0.6** 4.5± 0.4** 4.4± 0.4** 2000 ppm 4.6± 0.3** 4.5± 0.4** 4.2± 0.5** 4.3± 0.4** 3.9± 0.4** 4.2± 0.3** 4.3± 0.3**

PAGE: 5

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

(HAN260) BAIS 4

ANIMAL : MOUSE Crj:BDF1
UNIT : g

REPORT TYPE : A1 104

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

Group Name	Administration 102-7(7)	week-day(effective) 104-7(7)		
Control	5.0± 0.5	4.8± 0.4		
500 ppm	4.4± 0.5**	4.4± 0.4**		
1000 ppm	4.4± 0.4**	4.4± 0.4**		
2000 րրտ	4.1± 0.5**	4.1± 0.3**		
Significant differ	ence; *: P ≤ 0.05 *	*: P ≤ 0.01	Test of Dunnett	

(HAN260)

BAIS 4

APPENDIX D 2

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

ANIMAL : MOUSE Crj:BDF1

UNIT : g

REPORT TYPE : A1 104

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE: 7

up Name	Administration 1-7(7)	week-day(effective) 2-7(7)	3-7 (7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	3.0± 0.3	3.4± 0.2	3.4± 0.3	3.5± 0.2	3.4± 0.2	3.5± 0.2	3.7± 0.2
1000 ppm	3.1± 0.3	3.3± 0.2	3.4± 0.2	3.4± 0.2*	3.3± 0.4	3.5± 0.3	3.5± 0.2*
2000 ppm	2.8± 0.3*	3.1± 0.2**	3.2± 0.2**	3.2± 0.3**	3.2± 0.3★★	3.4± 0.3⊁*	3.4± 0.3**
4000 ppm	2.2± 0.3**	3.1± 0.3**	3.1± 0.2★★	2.9± 0.2**	3.0± 0.2**	3.1± 0.2**	3.2± 0.2**

(HAN260)

ANIMAL : MOUSE Crj:BDF1

UNIT : g

REPORT TYPE : A1 104

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE: 8

oup Name	Administration	week-day(effective)					
	8-7(7)	9-7 (7)	10-7(7)	11-7 (7)	12-7 (7)	13-7 (7)	14-7(7)
Control	3.7± 0.3	3.7± 0.3	3.7± 0.3	3.7± 0.3	3.7± 0.3	3.8± 0.3	3.9± 0.3
1000 ppm	3.6± 0.2*	3.7± 0.2	3.7± 0.3	3.7± 0.2	3.7± 0.4	3.8± 0.3	3.8± 0.3
2000 ppm	3.3± 0.3**	3.5± 0.3*	3.5± 0.3**	3.6± 0.3	3.6± 0.3*	3.7± 0.3	3.8± 0.3
4000 ppm	3.2生 0.2**	3.3± 0.3**	3.2± 0.2**	3.3± 0.2**	3.3± 0.2**	3.4± 0.3**	3.5± 0.3**

(HAN260)

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

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE: 9

oup Name	Administration	week-day(effective)					
	18-7 (7)	22-7 (7)	26-7 (7)	30-7 (7)	34-7(7)	38-7(7)	42-7(7)
Control	4.0± 0.3	4.0± 0.4	4.1± 0.4	4.0± 0.4	4.1± 0.4	4.2± 0.5	4.0± 0.4
1000 ppm	3.9± 0.3	3.8± 0.3	4.0± 0.3	3.8± 0.3**	3.9± 0.3*	4.0± 0.3	3.9± 0.4
2000 ppm	3.8± 0.2**	3.7± 0.3**	3.8± 0.3**	3.6± 0.3**	3.8± 0.3**	3.9± 0.3**	3.7± 0.4**
4000 ppm	3.5± 0.3**	3.4± 0.3**	3.6± 0.3**	3.4± 0.3**	3.6± 0.3**	3.6± 0.3**	3.5± 0.3**
Significant differe	nce; *: P ≤ 0.05 *	$*: P \leq 0.01$		Test of Dunnett			

(HAN260)

ANIMAL : MOUSE Crj:BDF1

UNIT : g
REPORT TYPE : AI 104
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE: 10

up Name		week-day(effective)					
	46-7 (7)	50-7 (7)	54-7 (7)	58-7 (7)	62-7(7)	66-7(7)	70-7 (7)
Control	4.0± 0.5	4.1± 0.5	4.1± 0.4	3.8± 0.4	3.8± 0.5	4.1± 0.5	4.2± 0.4
1000 ppm	4.0± 0.5	3.8± 0.4*	3.7± 0.4**	3.4± 0.4**	3.5± 0.5*	3.7± 0.5**	3.9± 0.4**
2000 ppm	3.7± 0.3**	3.6± 0.4**	3.5± 0.3**	3.2± 0.3**	3.3± 0.3**	3.5± 0.3**	3.7± 0.3**
4000 ррт	3.5± 0.3**	3.4± 0.3**	3.3± 0.3★★	3.1± 0.4**	3.1± 0.4**	3.4± 0.3**	3.4± 0.4**
Significant difference;	$*: P \leq 0.05$	** : P ≤ 0.01		Test of Dunnett			

(HAN260)

ANIMAL : MOUSE Crj:BDF1

UNIT : g
REPORT TYPE : A1 104

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE: 11

up Name		reek-day(effective)	00 5 (5)	00.5(5)	00 5 (5)		
	74-7 (7)	78-7 (7)	82-7 (7)	86-7 (7)	90-7 (7)	94-7 (7)	98-7 (7)
Control	4.1± 0.6	4.0± 0.7	4.0± 0.6	4.2± 0.6	4.1± 0.8	4.1± 0.6	4.0± 0.8
1000 ppm	3.9± 0.5*	3.8± 0.5	3.8± 0.4	3.7± 0.5**	3.7± 0.5**	3.8± 0.5	3.7± 0.5
2000 ppm	3.6± 0.5**	3.5± 0.4**	3.6± 0.4**	3.6± 0.5**	4.0± 0.6	3.7± 0.6*	3.6± 0.6*
4000 ррш	3.4± 0.4**	3.3± 0.4**	3.3± 0.5**	3.3± 0.5★★	3.7± 0.4**	3.3± 0.3**	3.2± 0.4**
Significant differen	ice; $*: P \leq 0.05$ **	$*: P \leq 0.01$		Test of Dunnett			

(HAN260)

ANIMAL : MOUSE Crj:BDF1

UNIT : g
REPORT TYPE : A1 104

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE: 12

Froup Name	Administration w 102-7(7)	eek-day(effective) 104-7(7)	
Control	4.0± 0.7	4.4± 0.6	
1000 ppm	3.7± 0.5	3.6± 0.8★★	
2000 ppm	3.7± 0.5	3.7± 0.6**	
4000 рут	3.2± 0.4**	3.1± 0.4**	
Significant differe	nce; *: P ≤ 0.05 *	: P ≤ 0.01	Test of Dunnett

(HAN260)

APPENDIX E 1

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

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

CHEMICAL INTAKE CHANGES (SUMMARY) ALL ANIMALS

Cr.1:RDi-I

SEX : MALE

PAGE: 1

roup Name	Administration (5	6	7
	1	2	3	4			
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
500 ppm	0.093± 0.017	0.097± 0.015	0.096± 0.016	0.087± 0.013	0.076± 0.021	0.085± 0.016	0.075± 0.019
1000 ppm	0.148± 0.020	0.152± 0.023	0.153± 0.029	0.137± 0.022	0.129± 0.035	0.141± 0.025	0.129± 0.031
2000 բբա	0.211± 0.026	0.233± 0.050	0.227± 0.057	0.228± 0.044	0.213± 0.054	0.242± 0.052	0.226± 0.045

(HAN300)

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

REPORT TYPE : A1 104

SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

Froup Name	Administration	(weeks)			10	13	14
	8	9	10	11	12	13	
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
500 ppm	0.074± 0.012	0.073± 0.014	0.076± 0.018	0.067± 0.010	0.066± 0.010	0.065± 0.012	0.063± 0.009
1000 ppm	0.128± 0.025	0.123± 0.025	0.126± 0.026	0.121± 0.021	0.116± 0.018	0.118± 0.019	0.109± 0.015
2000 թրա	0.217± 0.046	0.233± 0.054	0.221± 0.050	0.209± 0.050	0.203± 0.043	0.209± 0.043	0.206± 0.053

(HAN300)

BAIS 4

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

STUDY NO. : 0372

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

REPORT TYPE : A1 104

SEX : MALE

roup Name	Administration	(weeks)				20	42
	18	22	26 	30	34	38	42
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
500 ppm	0.053± 0.007	0.048± 0.006	0.048± 0.009	0.046± 0.006	0.046± 0.005	0.050± 0.010	0.046± 0.005
1000 ppm	0.098± 0.015	0.091± 0.012	0.089± 0.014	0.084± 0.014	0.087± 0.012	0.088± 0.014	0.087± 0.013
2000 ապա	0.185± 0.031	0.169± 0.026	0.166± 0.028	0.164± 0.023	0.172± 0.024	0.170± 0.025	0.172± 0.022

PAGE: 3

(HAN300) BAIS 4

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

SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

roup Name	Administration	(weeks)					
	46	50 	54	58	62	66	70
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
500 ppm	0.044± 0.005	0.044± 0.005	0.042± 0.004	0.045± 0.010	0.039± 0.011	0.041± 0.007	0.043± 0.006
1000 ppm	0.087± 0.012	0.085± 0.014	0.083± 0.010	0.088± 0.015	0.085± 0.018	0.087± 0.012	0.089± 0.014
2000 ppm	0.176± 0.025	0.162± 0.024	0.164± 0.021	0.170± 0.021	0.170± 0.036	0.180± 0.019	0.183± 0.028

(HAN300)

BAIS 4

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

SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

Group Name	Administration	(weeks)					
	74	78	82	86	90	94	98
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
500 ppm	0.042± 0.008	0.044± 0.007	0.044± 0.007	0.043± 0.011	0.047± 0.008	0.045± 0.007	0.046± 0.009
1000 ppm	0.088± 0.014	0.090± 0.017	0.090± 0.017	0.088± 0.020	0.101± 0.029	0.099± 0.017	0.103± 0.019
2000 թբա	0.184± 0.038	0.178± 0.030	0.190± 0.040	0.184± 0.060	0.206± 0.077	0.213± 0.034	0.224± 0.040

(HAN300) BAIS 4

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

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

SEX : MALE

Group Name	Administration (weeks) 104
Control	0.000± 0.000	0.000± 0.000
500 ppm	0.046± 0.009	0.046± 0.009
1000 ppm	0.108± 0.020	0.104± 0.021
2000 թբա	0.237± 0.058	0.237± 0.055

PAGE: 6

(HAN300) BAIS 4

APPENDIX E 2

CHEMICAL INTAKE CHANGES: SUMMARY, MOUSE: FEMALE

(2-YEAR STUDY)

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

SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 7

roup Name	Administration	(weeks)					
	1	2	3	4	5	6	7
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
1000 ppm	0.175± 0.020	0.166± 0.019	0.160± 0.015	0.156± 0.014	0.149± 0.041	0.157± 0.025	0.155± 0.025
2000 ppm	0.244± 0.037	0.249± 0.061	0.233± 0.033	0.242± 0.036	0.224± 0.082	0.253± 0.036	0.246± 0.034
4000 ppm	0.386± 0.051	0.391± 0.037	0.377± 0.040	0.404± 0.064	0.379± 0.065	0.416± 0.073	0.385± 0.037

(HAN300)

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

SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

roup Name	Administration	(weeks)					
	8	9	10	11	12	13	14
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
1000 ppm	0.156± 0.019	0.158± 0.028	0.149± 0.028	0.148± 0.017	0.149± 0.016	0.162± 0.035	0.153± 0.032
2000 ppm	0.240± 0.040	0.243± 0.047	0.242± 0.045	0.240± 0.028	0.238± 0.028	0.250± 0.067	0.259± 0.061
4000 ppm	0.381± 0.039	0.396± 0.062	0.375± 0.107	0.397± 0.059	0.394± 0.043	0.418± 0.089	0.390± 0.066

(HAN300)

BAIS 4

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

SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

roup Name	Administration	(weeks)					
	18	22	26	30	34	38	42
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
1000 ppm	0.135± 0.021	0.127± 0.018	0.119± 0.023	0.120± 0.035	0.117± 0.027	0.115± 0.027	0.111± 0.029
2000 ppm	0.228± 0.028	0.218± 0.031	0.202± 0.031	0.212± 0.040	0.215± 0.041	0.198± 0.030	0.194± 0.032
4000 ppm	0.381± 0.032	0.347± 0.039	0.328± 0.054	0.352± 0.048	0.353± 0.039	0.345± 0.040	0.345± 0.042

PAGE: 9

(HAN300) BAIS 4

ANIMAL : MOUSE Crj:BDF1 UNIT : g / kg / d a y REPORT TYPE : A1 104

SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 10

Group Name	Administration	(weeks)					
	46	50	54	58	62	66	70
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
1000 ppm	0.106± 0.017	0.107± 0.022	0.101± 0.021	0.105± 0.018	0.100± 0.014	0.098± 0.015	0.094± 0.014
2000 ppm	0.202± 0.032	0. 195± 0. 029	0.194± 0.027	0.194± 0.030	0.196± 0.035	0.202± 0.046	0.193± 0.037
4000 ppm	0.351± 0.050	0.352± 0.044	0.337± 0.032	0.347± 0.048	0.358± 0.049	0.366± 0.045	0.352± 0.060

(HAN300)

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

REPORT TYPE : A1 104

SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)

 0.504 ± 0.092

ALL ANIMALS

Group Name	Administration	(weeks)					
	74	78	82	86	90	94	98
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
1000 ppm	0.096± 0.016	0.098± 0.018	0.098± 0.015	0.096± 0.016	0.098± 0.016	0.113± 0.020	0.105± 0.020
2000 ppm	0.195± 0.045	0.198± 0.046	0.208± 0.053	0.207± 0.054	0.219± 0.061	0.250± 0.075	0.266± 0.087

 0.558 ± 0.082

0.580± 0.106

 0.684 ± 0.090

(HAN300)

4000 ppm

0.398± 0.072

 0.437 ± 0.096

BAIS 4

0.640 ± 0.115

ANIMAL : MOUSE Crj:BDF1
UNIT : g / kg / d a y
REPORT TYPE : A1 104
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)

ALL ANIMALS

Group Name	Administration (102	weeks) 104		
Control	0.000± 0.000	0.000± 0.000		
1000 ppm	0. 108± 0. 023	0. 105± 0. 028		
2000 ppm	0.275± 0.066	0.282± 0.074		
4000 րթա	0.652± 0.131	0.638± 0.114		

(HAN300)

BAIS 4

APPENDIX F 1

HEMATOLOGY: SUMMARY, MOUSE: MALE

(2-YEAR STUDY)

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME: I SEX: MALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY) ALL ANIMALS (105W)

	NO. of Animals	RED BLOO I O⁵∕µú		HEMOGLOI g/dl	BIN	HEMATOC %	RIT	MCV f &		MCH pg						
Control	36	9.60±	0. 91	13.8±	1. 1	43.8±	3. 2	45.8±	1.9	14.4±	0.5	31.5±	0. 7	1911±	411	
500 ppm	38	9.59±	1.28	13.6±	1.5	43.2±	4. 2	45.3±	2.9	14.2±	0.7	31.4±	1.0	1985±	418	
1000 ppm	42	9. 43±	1.92	13.5±	2. 3	43.4±	6.8	46. 9±	6.3	14.5±	i. 1	31.1±	1.3	2087±	470	
2000 ppm	39	9.10±	0.84**	13.3±	1. 2**	42.7±	3. 9	46.9±	1. 2**	14.6±	0.3	31.1±	0.6**	2279±	303**	

(HCL070)

BATS 4

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

REPORT TYPE : AI

HEMATOLOGY (SUMMARY) ALL ANIMALS (105W)

				N-SEG		EOSTNO		BAS0		MONO		LYMPIIO		OTHER	
36	4.47± 8.86	1±	2	30±	17	2±	1	0±	0	5±	3	60±	18	2±	9
38	2.96± 1.61	Ι±	ı	29±	13	2±	3	0±	0	5±	2	61±	16	3±	9
42	3.05± 2.90	2±	3	36±	14	1 土	i	0土	0	4 <u>+</u>	2	56土	15	l±	2
39	2.00± 1.31**	2±	2	42±	17**	1±	3**	0±	0	3±	1**	52±	17	0±	1
	38 42	38 2.96± 1.61 42 3.05± 2.90	38 2.96± 1.61 1± 42 3.05± 2.90 2±	38 2.96± 1.61 1± 1 42 3.05± 2.90 2± 3	38	38	38	38	38	38	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	36 4.47± 8.86 1± 2 30± 17 2± 1 0± 0 5± 2 61± 16 38 2.96± 1.61 1± 1 29± 13 2± 3 0± 0 5± 2 61± 16 42 3.05± 2.90 2± 3 36± 14 1± 1 0± 0 4± 2 56± 15	$\begin{array}{cccccccccccccccccccccccccccccccccccc$

(HCL070)

APPENDIX F 2

HEMATOLOGY: SUMMARY, MOUSE: FEMALE

(2-YEAR STUDY)

HEMATOLOGY (SUMMARY) ALL ANIMALS (105W)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1 MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

PAGE: 3

up Name	NO. of Animals	RED BLOOD (1 05/µl	CELL	HEMOGLOF g/dl	BIN	HEMATOC %	RIT	MCV f &		MCH pg		MCHC g/dl	<u></u> .	PLATELET 1 03/µk	
Control	22	9.82± 1.	99	14.1±	2. 3	44.5±	7.1	45.7±	2.3	14.4±	0.6	31.6±	1.1	1210±	273
1000 ppm	27	9.30± 1.	. 22	13.6±	1.7	43. 2±	4.6	46.7±	2.8	14.7生	0.6	31.5±	1. 1	1329±	374
2000 ppm	25	8.94 <u>-1</u> 1.	. 90	12.9 <u>-1</u> :	2. 7	41.6±	8.0	47.4 <u>±</u>	5. 1	14.6±	0.7	30.9±	1.6*	1399±	453
4000 ppm	28	9.37± 0.	. 85	13.4±	1. 2**	43.7±	3. 9	46.7±	2.1**	14.4±	0.7	30.7±	0.6**	1641±	454**

(HCI_070)

ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY) ALL ANIMALS (105W)

2.13± 1.63	1±	2												
		6	29±	12	3±	4	0±	0	5±	2	58±	15	3±	10
4.50± 11.15	2±	2	30±	12	Ι±	1	0±	0	5±	3	58±	15	4 <u>±</u>	14
4.17± 4.18	2生	2	35±	14	1土	[**	0±	0	4±	2	56±	14	2±	4
1.94± 1.51	2±	1	40±	19	1±	[**	0±	0	4±	2	52±	19	2±	8
	4.17± 4.18	4. 17± 4. 18 2±	4. 17± 4. 18 2± 2	4. 17 ± 4. 18 2± 2 35 ±	4.17± 4.18 2± 2 35± 14	4.17± 4.18 2± 2 35± 14 1±	4.17± 4.18 2± 2 35± 14 1± 1**	4.50± 11.15	4.50± 11.15	4.50± 11.15 2± 2 30± 12 1= 1 4.17± 4.18 2± 2 35± 14 1± 1** 0± 0 4±	4.50± 11.15	4.50± 11.15	4.50± 11.15 2± 2 30± 12 1± 1 0± 0 4± 2 56± 14 4.17± 4.18 2± 2 35± 14 1± 1** 0± 0 4± 2 56± 14	4.50± 11.15

PAGE: 4

(HCL070)

APPENDIX G 1

BIOCHEMISTRY: SUMMARY, MOUSE: MALE

(2-YEAR STUDY)

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME: 1 SEX: MALE

REPORT TYPE : A1

PAGE: 1

up Name	NO. of Animals	TOTAL P g/dl	ROTEIN	ALBUMIN g/dl		A/G RAT	10	T-BILII mg/dl	RUBIN	GLUCOSE mg/dl		T-CHOLES mg/dl	TEROL	TRIGLYCE mg/dl	RIDE
Control	37	5.1±	0.6	2.9±	0. 4	1.3±	0.2	0.13±	0. 02	193±	32	113±	38	47±	27
500 ppm	38	5.3生	0.7	3.0±	0.4	1.3±	0. 1	0.13±	0. 03	198±	35	117±	51	41±	24
1000 ppm	42	5.3±	0.9	3.0±	0.5*	1.3±	0.2	0.15±	0.10	179±	50	127±	68	41土	16
2000 ppm	39	5.6±	0.8**	3.2±	0.3**	1.3±	0.2	0.14±	0.04	185±	43	129±	50	31±	11**

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME: 1 SEX : MALE

REPORT TYPE : AI

up Name	NO. of Animals	PHOSPHOI mg/dl	JPID	GOT I U / £	1	GPT IU/£		LDH IU/J	2	ALP IU/£		G-GTP IU/1		CPK IU/L	
Control	37	210±	58	88±	167	49±	77	343±	262	124±	28	1±	1	42±	13
500 ppm	38	220±	76	127±	224	135±	355	620±	1341	220±	244**	2±	1	47±	20
1000 ppm	42	243±	117	174±	355	178±	514**	752±	1200	337±	396**	2±	1	120±	337*
2000 ррв	39	241±	80	119±	264	119±	300**	612±	1125	279±	182**	2±	1	84±	129**
Significant	difference;	*: P ≤ (), 05	**: P ≤ 0.0	01			Test of Du	nnett						

(HCL074)

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : AL

oup Name	NO. of Animals	UREA NI'	UREA NITROGEN mg/dl		SODIUM m Eq / l		POTASSIUM mEq/l		CHLORIDE m Eq / L		CALCIUM mg/dl		IC PHOSPHORUS
Control	37	23.4±	9. 4	152±	1	4.3±	0.4	122±	3	9.0±	0.5	6.4±	0.8
500 ppm	38	22.8±	3. 3	152±	1	4.1±	0.3	122±	3	9.1±	0.5	6.2±	0.6
1000 ppm	42	28. 4 <u>-1</u> -	12. 1**	152±	3	4.2±	0.4	123±	4	9.1±	0.7	6.3±	0.7
2000 ppm	39	30.9±	11.3**	153±	2**	4.0±	0.4**	123±	3	9.2±	0.5	6.4±	0.9
Significant	difference;	*: P ≤ 0	0. 05	t=: P ≤ 0.0				Test of Dum	nett				
													B/

(HCL074)

APPENDIX G 2

BIOCHEMISTRY: SUMMARY, MOUSE: FEMALE

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME: 1 SEX: FEMALE

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

oup Name	NO. of Animals	TOTAL, P g/dl	ROTEIN	ALBUMIN g∕dl		A/G RAT	10	T-BILII mg/dl	RUBIN	GLUCUSE mg/dl		T-CHOLES mg/dl	STEROL	TRIGLYCH mg/dL	RIDE
Control	23	5.5±	1. 1	2.9±	0. 3	1.3±	0.3	0.13±	0.02	131±	24	85±	37	33±	28
1000 ppm	27	5.3±	0.5	3.1±	0.3	1.4±	0.2	0.15±	0.07	147±	35	93±	37	32±	14
2000 ррт	26	5.4±	0.9	3.2±	0.5**	1.5±	0. 2	0.16±	0. 12	144土	36	133生	81**	44 1	47
4000 ppm	31	5.7±	0. 7*	3.5±	0. 4**	1.6±	0. 2**	0.15±	0.04	144±	36	169±	74**	24±	13

(HCL074)

BATS 4

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME: 1

SEX : FEMALE

REPORT TYPE : A1

oup Name	NO. of Animals	PHOSPHOL mg/dl	JPID	GOT I U / L		GPT IU/2		LDH I U / A	2	ALP IU/2		G-GTP I U/l		CPK IU/1	
Control	23	163±	61	87±	36	40±	23	386±	304	171±	53	2±	1	73±	65
1000 ppm	27	177±	53	130±	203	74±	123	646±	879	254±	88*	2±	1	64±	43
2000 ppm	26	244 <i>-</i> ±	116**	133生	151	120±	189	537±	451	443±	468**	3 土	3	117生	184
4000 ppm	31	286±	104**	190±	224	207±	316**	867±	1112	598±	559**	4±	6	112±	88**

PAGE: 5

(HCL074)

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME: 1 SEX : FEMALE

PAGE: 6 REPORT TYPE : A1

Group Name	NO. of Animals	UREA NITROGEN mg/dl	SODIUM mEq/l		POTASSI mEq/s		CHLORIDE m Eq / 2		CALCIUM mg/dL		INORGAN mg/dl	IC PHOSPHORUS
Control	23	23.6± 24.3	151±	2	4. 2±	0.5	123±	3	9.4±	0.6	6.6±	1.3
mqq 0001	27	24.5± 10.6	151±	2	4.0±	0.4	123±	4	9.3±	0.6	6.3±	1.5
2000 ppm	26	27.5生 11.9**	152±	3	3.9±	0.4	124±	5	9.6±	0.5	6. 2±	1.4
4000 ppm	31	30.7± 13.9₩	155±	4**	3.9±	0.4	126±	4**	9.6±	0.6	6.1±	0.9
Significant	difference ;	*: P ≤ 0.05 *	⇒ : P ≤ 0.0	1			Test of Dunn	ett				PATS

BATS 4 (HCL074)

APPENDIX H 1

URINALYSIS: SUMMARY, MOUSE: MALE

STUDY NO. : 0372 URINALYSIS

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME: 1

SEX: MALE REPORT TYPE: A1

oup Name	NO. of	pH_								Pro	teir					Glu	cose	e			Keto	ne b	ody			0	cult	t b1	ood	
	Animals	5. 0	6. 0	6.5	7.0	7. 5	8.0	8.5	CHI	_	± -	+ 2	+ 3+	4+	CHI	_	±	+ 2	+ 3+	4+ CHI	- ±	+	2+	3+ 4+	CHI		±	+	2+ 3	+ Cl
Control	38	0	1	6	16	14	1	0		0	4 2	4 4	3 2	: 0		38	0	0	0 0	0	23 1	3 2	0	0 0		3	4 0	0	0 4	4
500 ppm	38	0	1	19	12	6	0	0	*	0	0 3	0 .	7 1	0		38	0	0	0 0	0	17 1	8 3	0	0 0		3	7 0	1	0)
1000 ppm	42	0	7	28	7	0	0	0	**	0	2 2	9 1) 1	. 0		42	0	0	0 0	0	21 1	6 5	0	0 0		3	5 1	1	2	2
2000 ppm	39	0	6	25	8	0	0	0	**	0	4 2	5 1	0	0		39	0	0	0 0	0	19 1	1 9	0	0 0		3	5 0	0	2	2

PAGE: 1

(HCL101) BAIS 4

URINALYSIS

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME: 1

SEX : MALE

REPORT TYPE : AI

PAGE: 2 Group Name NO. of Urobilinogen Animals ± + 2+ 3+ 4+ CHI Control 38 38 0 0 0 0 500 ppm 38 38 0 0 0 0 1000 ppm 42 0 0 0 0 2000 ppm 39 39 0 0 0 0 Significant difference ; $*: P \leq 0.05$ ** : P ≤ 0.01 Test of CHI SQUARE

BAIS 4

(IICL101)

APPENDIX H 2

URINALYSIS: SUMMARY, MOUSE: FEMALE

STUDY NO. : 0372 URINALYSIS

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME: 1

roup Name	NO. of	_Hq								Protein	Glucose	Ketone body	Occult blood
	Animals	5.0	6.0	6. 5	7. 0	7. 5	8.0	8.5	CHI	- ± + 2+ 3+ 4+ CHI	- ± + 2+ 3+ 4+ CHI	- ± + 2+ 3+ 4+ CHI	- ± + 2+ 3+ CHI
Control	27	0	1	3	6	5	10	2		0 0 9 16 2 0	27 0 0 0 0 0	3 20 4 0 0 0	20 3 0 1 3
1000 ppm	29	0	2	14	8	4	1	0	**	0 2 9 16 2 0	29 0 0 0 0 0	2 18 7 2 0 0	20 4 0 1 4
2000 ppm	28	0	9	16	3	0	0	0	**	0 6 10 11 1 0	28 0 0 0 0 0	3 22 1 2 0 0	24 1 0 1 2
4000 ppm	34	0	25	9	0	0	0	0	**	0 13 16 4 1 0 **	34 0 0 0 0 0	13 20 1 0 0 0 *	25 1 0 0 8

(HCL101) BAIS 4 STUDY NO. : 0372 URINALYSIS

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME: 1

SEX : FEMALE REPORT TYPE : AL

PAGE: 4 Group Name NO. of Urobilinogen ± + 2+ 3+ 4+ CHI Animals Control 27 27 0 0 0 0 1000 ppm 29 29 0 0 0 0 2000 ppm 28 0 0 0 0 4000 ppm 34 34 0 0 0 0 Test of CHI SQUARE Significant difference ; $*: P \le 0.05$ $** : P \leq 0.01$

(HCL101) BAIS 4

APPENDIX I 1

GROSS FINDINGS: SUMMARY, MOUSE: MALE ALL ANIMALS

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1

SEX : MALE

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

EX :	MALE				PAGE :
rgan	Findings	Group Name Control NO. of Animals 50 (%)	500 ppm 50 (%)	1000 ppm 50 (%)	2000 ppm 50 (%)
kin/app	ulcer	0 (0)	1 (2)	0 (0)	1 (2)
	thick	0 (0)	0 (0)	0 (0)	1 (2)
	scab	0 (0)	1 (2)	0 (0)	0 (0)
ubcutis	mass	1 (2)	0 (0)	1 (2)	1 (2)
ing	red zone	0 (0)	0 (0)	1 (2)	0 (0)
	red patch	0 (0)	1 (2)	1 (2)	0 (0)
	nodule	7 (14)	6 (12)	5 (10)	4 (8)
mpli node	enlarged	4 (8)	6 (12)	6 (12)	7 (14)
leen	enlarged	2 (4)	4 (8)	3 (6)	1 (2)
	black zone	1 (2)	1 (2)	2 (4)	2 (4)
	nodule	1 (2)	0 (0)	2 (4)	0 (0)
	accentuation of white pulp	0 (0)	2 (4)	1 (2)	3 (6)
eart	white zone	0 (0)	0 (0)	0 (0)	1 (2)
	deformed	0 (0)	1 (2)	0 (0)	0 (0)
	dilated	0 (0)	0 (0)	1 (2)	0 (0)
alivary gl	nodule	0 (0)	0 (0)	1 (2)	0 (0)
stomach	nodule	1 (2)	0 (0)	0 (0)	0 (0)
	thick	1 (2)	0 (0)	0 (0)	0 (0)
odenum	nodulo	1 (2)	0 (0)	0 (0)	0 (0)
all intes	nodule	1 (2)	1 (2)	3 (6)	1 (2)
	dilated	0 (0)	0 (0)	0 (0)	1 (2)
ver	enlarged	0 (0)	1 (2)	I (2)	0 (0)

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

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

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SEX :	MALE			·	PAGE :
Organ	Findings	Group Name Control NO. of Animals 50 (%)	500 ppm 50 (%)	1000 ppm 50 (%)	2000 ppm 50 (%)
liver	white zone	1 (2)	4 (8)	6 (12)	4 (8)
	red zone	2 (4)	1 (2)	0 (0)	1 (2)
	nodule	21 (42)	25 (50)	33 (66)	31 (62)
	cyst	0 (0)	1 (2)	0 (0)	0 (0)
cidney	red zone	0 (0)	1 (2)	0 (0)	0 (0)
	cyst	1 (2)	0 (0)	1 (2)	0 (0)
	granular	0 (0)	0 (0)	1 (2)	0 (0)
	hydronephrosis	2 (4)	2 (4)	2 (4)	4 (8)
rin bladd	nodule	0 (0)	1 (2)	0 (0)	0 (0)
	urine:marked retention	2 (4)	3 (6)	0 (0)	1 (2)
ituitary	enlarged	0 (0)	0 (0)	1 (2)	I (2)
estis	enlarged	0 (0)	1 (2)	0 (0)	0 (0)
pididymis	nodule	1 (2)	0 (0)	1 (2)	1 (2)
rep/cli gl	nodule	9 (18)	9 (18)	2 (4)	6 (12)
rain	hemorrháge	0 (0)	1 (2)	0 (0)	0 (0)
	nodule	1 (2)	0 (0)	0 (0)	0 (0)
pinal cord	hemorrhage	0 (0)	1 (2)	0 (0)	0 (0)
eriph nerv	nodule	0 (0)	1 (2)	0 (0)	0 (0)
arder gl	onlargod	1 (2)	2 (4)	1 (2)	0 (0)
	nodule	2 (4)	3 (6)	1 (2)	1 (2)
ertebra	mass	0 (0)	0 (0)	0 (0)	1 (2)
ediastinum	mass	1 (2)	0 (0)	0 (0)	1 (2)

STUDY NO. : 0372
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE: 3

Organ	Findings	Group Name Control NO. of Animals 50 (%)	500 ppm 50 (%)	1000 ppm 50 (%)	2000 ppm 50 (%)
eritoneum	nodulo	1 (2)	0 (0)	0 (0)	0 (0)
bdominal c	hemorrhage		0 (0)	0 (0)	0 (0)
	ascites	2 (4)	0 (0)	0 (0)	2 (4)
oracic ca	pleural fluid	1 (2)	1 (2)	3 (6)	2 (4)
ole body	anemic	0 (0)	2 (4)	1 (2)	1 (2)

BAIS 4

APPENDIX I 2

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

ANIMAL : MOUSE Crj:BDF1

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

REPORT TYPE : A1
SEX : FEMALE

gan	Findings	Group Name Control 	1000 ppm 50 (%)	2000 ppm 50 (%)	4000 ppm 50 (%)
in/app	nodule	1 (2)	0 (0)	0 (0)	0 (0)
	thick	1 (2)	0 (0)	0 (0)	0 (0)
cutis	edema	5 (10)	6 (12)	2 (4)	0 (0)
	mass	0 (0)	1 (2)	1 (2)	2 (4)
	White	0 (0)	0 (0)	1 (2)	0 (0)
	white zone	0 (0)	0 (0)	1 (2)	0 (0)
	red zone	0 (0)	0 (0)	1 (2)	0 (0)
	пodule	2 (4)	1 (2)	3 (6)	1 (2)
h node	enlarged	11 (22)	8 (16)	4 (8)	3 (6)
us	enlarged	1 (2)	0 (0)	0 (0)	0 (0)
en	enlarged	5 (10)	7 (14)	3 (6)	2 (4)
	nodule	1 (2)	1 (2)	0 (0)	1 (2)
	accentuation of white pulp	0 (0)	1 (2)	4 (8)	1 (2)
stomach	nodule	0 (0)	1 (2)	2 (4)	0 (0)
	ulcer	1 (2)	0 (0)	0 (0)	0 (0)
tomach	ulcer	1 (2)	0 (0)	0 (0)	0 (0)
l intes	nodu l e	1 (2)	1 (2)	1 (2)	0 (0)
	dilated	0 (0)	1 (2)	0 (0)	0 (0)
n	nodulo	0 (0)	1 (2)	1 (2)	0 (0)
r	enlarged	4 (8)	4 (8)	3 (6)	3 (6)
	atrophic	0 (0)	1 (2)	0 (0)	0 (0)
	white zone	6 (12)	9 (18)	6 (12)	5 (10)

SEX

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 : FEMALE

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

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PAGE: 5 Group Name Control 1000 ppm 2000 ppm 4000 ppm Findings_ Organ_ NO. of Animals 50 (%) 50 (%) 50 (%) 50 (%) liver red zone 2 (4) 0 (0) 2 (4) 4 (8) brown zone 0 (0) i (2) 0 (0) 0 (0) nodule 10 (20) 23 (46) 31 (62) 36 (72) cyst 0 (0) 1 (2) 0 (0) 1 (2) rough 1 (2) 0 (0) 0 (0) 0 (0) nodular 1 (2) 0 (0) 0 (0) 0 (0) kidney enlarged 0 (0) 2 (4) 2 (4) 0 (0) atrophic 0 (0) 1 (2) 0 (0) 0 (0) white zone 0 (0) 1 (2) 0 (0) 1 (2) nodule 1 (2) 0 (0) 1 (2) 0 (0) cyst 0 (0) 0 (0) 0 (0) 1 (2) hydronephrosis 2 (4) 7 (14) 12 (24) 7 (14) ureter dilated 0 (0) 0 (0) 1 (2) 0 (0) thick 0 (0) 0 (0) 1 (2) 0 (0) urin bladd urine:marked retention 1 (2) 0 (0) 0 (0) 0 (0) pituitary enlarged 3 (6) 2 (4) 0 (0) 1 (2) red 1 (2) 0 (0) 0 (0) 0 (0) red zone 1 (2) 0 (0) 0 (0) 0 (0) black zone 0 (0) 1 (2) 0 (0) 0 (0) nodule 2 (4) 0 (0) 1 (2) 0 (0) ovary enlarged 5 (10) 9 (18) 5 (10) 2 (4) cyst

11 (22)

4 (8)

3 (6)

3 (6)

ANIMAL : MOUSE Cr.j:BDF1

REPORT TYPE : AI

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

SEX : FEMALE

gan	Findings	Group Name Control NO. of Animals 50 (%)	1000 ppm 50 (%)	2000 ppm 50 (%)	4000 ppm 50 (%)
erus	nodule	10 (20)	20 (40)	12 (24)	9 (18)
	nodular	1 (2)	0 (0)	0 (0)	0 (0)
	dilated lumen	1 (2)	0 (0)	0 (0)	0 (0)
rder gl	enlarged	1 (2)	1 (2)	i (2)	1 (2)
	nodule	0 (0)	0 (0)	1 (2)	2 (4)
mbal gl	nodule	1 (2)	0 (0)	0 (0)	0 (0)
ne	nodule	0 (0)	0 (0)	0 (0)	1 (2)
diastinum	mass	4 (8)	3 (6)	0 (0)	0 (0)
ritoneum	nodule	0 (0)	0 (0)	1 (2)	0 (0)
	thick	3 (6)	1 (2)	0 (0)	0 (0)
dominal c	hemorrhage	2 (4)	2 (4)	3 (6)	0 (0)
	ascites	10 (20)	6 (12)	5 (10)	2 (4)
oracic ca	hemorrhage	1 (2)	0 (0)	1 (2)	0 (0)
	mass	1 (2)	0 (0)	0 (0)	0 (0)
	pleural fluid	11 (22)	5 (10)	1 (2)	1 (2)
her	forelimb:nodule	0 (0)	0 (0)	1 (2)	0 (0)
	lower jaw:nodule	0 (0)	0 (0)	0 (0)	1 (2)
	nose:nodule	1 (2)	0 (0)	0 (0)	0 (0)
le body	anemic	1 (2)	0 (0)	0 (0)	0 (0)

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APPENDIX I 3

GROSS FINDINGS: SUMMARY, MOUSE: MALE: SACRIFICED ANIMALS

STUDY NO. : 0372 GROSS FINDINGS (SUMMARY)
ANIMAL : MOUSE Crj:EDF1 SACRIFICED ANIMALS (105W)

REPORT TYPE : A1 SEX : MALE

gan	Findings	Group Name Control NO. of Animals 38 (%)	500 ppm 38 (%)	1000 ppm 42 (%)	2000 ppm 39 (%)
in/app	thick	0 (0)	0 (0)	0 (0)	1 (2)
ing	red zone	0 (0)	0 (0)	1 (2)	1 (3)
•	nodule	5 (13)	5 (13)		0 (0)
mph node	enlarged			5 (12)	4 (10)
leen	enlarged	2 (5)	4 (11)	5 (12)	6 (15)
reen	•	1 (3)	2 (5)	3 (7)	1 (3)
	black zone	1 (3)	1 (3)	2 (5)	2 (5)
	nodule	0 (0)	0 (0)	2 (5)	0 (0)
	accentuation of white pulp	0 (0)	2 (5)	1 (2)	3 (8)
stomach	nodule	1 (3)	0 (0)	0 (0)	0 (0)
odenum	nodule	1 (3)	0 (0)	0 (0)	0 (0)
all intes	nodule	0 (0)	1 (3)	3 (7)	0 (0)
ver	enlarged	0 (0)	0 (0)	1 (2)	0 (0)
	white zone	1 (3)	3 (8)	5 (12)	4 (10)
	red zone	2 (5)	1 (3)	0 (0)	1 (3)
	nodule	13 (34)	21 (55)	29 (69)	28 (72)
	cyst	0 (0)	1 (3)	0 (0)	0 (0)
dney	red zone	0 (0)	1 (3)	0 (0)	0 (0)
	cyst	1 (3)	0 (0)	1 (2)	0 (0)
	hydronephrosis	1 (3)	1 (3)	1 (2)	1 (3)
in bladd	urine:marked retention	1 (3)	0 (0)	0 (0)	0 (0)
tuitary	enlarged	0 (0)	0 (0)	0 (0)	1 (3)
stis	enlarged	0 (0)	1 (3)	0 (0)	0 (0)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (105W)

SEX : MALE

Organ	Findings	Group Name NO. of Animals	Control 38 (%)	500 ppm 38 (%)	1000 ppm 42 (%)	2000 ppm 39 (%)
epididymis	nodule		1 (3)	0 (0)	1 (2)	1 (3)
prep/cli gl	nodule		9 (24)	9 (24)	2 (5)	6 (15)
Harder gl	enlarged		1 (3)	2 (5)	1 (2)	0 (0)
	nodule		2 (5)	2 (5)	1 (2)	1 (3)
thoracic ca	pleural fluid		0 (0)	0 (0)	2 (5)	0 (0)

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APPENDIX I 4

GROSS FINDINGS: SUMMARY, MOUSE: FEMALE: SACRIFICED ANIMALS

STUDY NO. : 0372
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (105W)

rgan	Findings	Group Name Control NO. of Animals 24 (%)	1000 ppm 29 (%)	2000 ppm 28 (%)	4000 ppm 34 (%)
kin/app	nodule	1 (4)	0 (0)	0 (0)	0 (0)
	thick	1 (4)	0 (0)	0 (0)	0 (0)
bcutis	mass	0 (0)	0 (0)	1 (4)	0 (0)
ng	white	0 (0)	0 (0)	1 (4)	0 (0)
	white zone	0 (0)	0 (0)	1 (4)	0 (0)
	nodule	2 (8)	1 (3)	1 (4)	0 (0)
mph node	enlarged	3 (13)	3 (10)	3 (11)	2 (6)
leen	enlarged	2 (8)	2 (7)	0 (0)	1 (3)
	nodu1e	0 (0)	1 (3)	0 (0)	1 (3)
	accentuation of white pulp	0 (0)	1 (3)	4 (14)	1 (3)
restomach	nodule	0 (0)	1 (3)	2 (7)	0 (0)
stomach	ulcer	1 (4)	0 (0)	0 (0)	0 (0)
mall intes	nodule	0 (0)	0 (0)	1 (4)	0 (0)
ecum	nodule	0 (0)	0 (0)	1 (4)	0 (0)
iver	atrophic	0 (0)	1 (3)	0 (0)	0 (0)
	white zone	1 (4)	4 (14)	3 (11)	3 (9)
	red zone	0 (0)	0 (0)	2 (7)	2 (6)
	nodu1e	5 (21)	15 (52)	18 (64)	28 (82)
	cyst	0 (0)	1 (3)	0 (0)	1 (3)
dney	enlarged	0 (0)	1 (3)	0 (0)	0 (0)
	white zone	0 (0)	1 (3)	0 (0)	1 (3)
	nodule	0 (0)	0 (0)	1 (4)	0 (0)

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (105W)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1
SEX : FEMALE

)rgan	Findings	Group Name Control NO. of Animals 24 (%)	1000 ppm 29 (%)	2000 ppm 28 (%)	4000 ppm 34 (%)
cidney	cyst	0 (0)	0 (0)	0 (0)	1 (3)
	hydronephrosis	2 (8)	3 (10)	5 (18)	2 (6)
pi tui tary	enlarged	1 (4)	1 (3)	0 (0)	0 (0)
	red zone	1 (4)	0 (0)	0 (0)	0 (0)
	black zone	0 (0)	1 (3)	0 (0)	0 (0)
	nodule	2 (8)	0 (0)	1 (4)	0 (0)
ovary	enlarged	0 (0)	3 (10)	1 (4)	i (3)
	cyst	6 (25)	1 (3)	2 (7)	3 (9)
iterus	nodule	3 (13)	9 (31)	3 (11)	4 (12)
	nodular	1 (4)	0 (0)	0 (0)	0 (0)
llarder gl	nodule	0 (0)	0 (0)	0 (0)	1 (3)
bone	nodule	0 (0)	0 (0)	0 (0)	1 (3)
abdominal c	ascites	2 (8)	1 (3)	1 (4)	0 (0)
thoracic ca	pleural fluid	0 (0)	1 (3)	0 (0)	0 (0)
other	nose:nodule	1 (4)	0 (0)	0 (0)	0 (0)

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APPENDIX I 5

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

ANIMAL : MOUSE Crj:BDF1

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

REPORT TYPE : A1
SEX : MALE

gan	Findings	Group Name Control NO. of Animals 12 (%)	500 ppm 12 (%)	1000 ppm 8 (%)	2000 ppm 11 (%)
in/app	ulcer	0 (0)	1 (8)	0 (0)	1 (9)
	scab	0 (0)	1 (8)	0 (0)	0 (0)
bcutis	mass	1 (8)	0 (0)	1 (13)	1 (9)
ing	red patch	0 (0)	1 (8)	1 (13)	0 (0)
	nodule	2 (17)	1 (8)	0 (0)	0 (0)
mph node	enlarged	2 (17)	2 (17)	1 (13)	1 (9)
leen	enlarged	1 (8)	2 (17)	0 (0)	0 (0)
	nodule	1 (8)	0 (0)	0 (0)	0 (0)
art	white zone	0 (0)	0 (0)	0 (0)	1 (9)
	deformed	0 (0)	1 (8)	0 (0)	0 (0)
	dilated	0 (0)	0 (0)	1 (13)	0 (0)
alivary gl	nodule	0 (0)	0 (0)	1 (13)	0 (0)
l stomach	thick	1 (8)	0 (0)	0 (0)	0 (0)
mall intes	nodule	1 (8)	0 (0)	0 (0)	1 (9)
	dilated	0 (0)	0 (0)	0 (0)	1 (9)
iver	enlarged	0 (0)	1 (8)	0 (0)	0 (0)
	white zone	0 (0)	1 (8)	1 (13)	0 (0)
	nodule	8 (67)	4 (33)	4 (50)	3 (27)
idney	granular	0 (0)	0 (0)	1 (13)	0 (0)
	hydronephrosis	1 (8)	1 (8)	1 (13)	3 (27)
rin bladd	nodule	0 (0)	1 (8)	0 (0)	0 (0)
	urine:marked retention	1 (8)	3 (25)	0 (0)	i (9)

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

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

)rgan	Findings	Group Name Control NO. of Animals 12 (%)	500 ppm 12 (%)	1000 ppm 8 (%)	2000 ppm 11 (%)
oituitary	enlarged	0 (0)	0 (0)	1 (13)	0 (0)
orain	hemorrhage	0 (0)	1 (8)	0 (0)	0 (0)
	nodule	1 (8)	0 (0)	0 (0)	0 (0)
spinal cord	hemorrhage	0 (0)	1 (8)	0 (0)	0 (0)
oeriph nerv	nodule	0 (0)	1 (8)	0 (0)	0 (0)
arder gl	nodule	0 (0)	1 (8)	0 (0)	0 (0)
ertebra	mass	0 (0)	0 (0)	0 (0)	1 (9)
ediastinum	Bass	1 (8)	0 (0)	0 (0)	1 (9)
eritoneum	nodule	1 (8)	0 (0)	0 (0)	0 (0)
bdominal c	hemorrhage	1 (8)	0 (0)	0 (0)	0 (0)
	ascites	2 (17)	0 (0)	0 (0)	2 (18)
horacic ca	pleural fluid	1 (8)	1 (8)	1 (13)	2 (18)
hole body	anemic	0 (0)	2 (17)	1 (13)	[(9)

BAIS 4

PAGE: 2

(HPT080)

APPENDIX I 6

GROSS FINDINGS : SUMMARY, MOUSE : FEMALE

DEAD AND MORIBUD ANIMALS

(2-YEAR STUDY)

GROSS FINDINGS (SUMMARY)

ANIMAL : MOUSE Crj:BDF1

DEAD AND MORIBUND ANIMALS (0-105W)

REPORT TYPE : A1 SEX : FEMALE

Organ	Findings	Group Name Control NO. of Animals 26 (%)	1000 ppm 21 (%)	2000 ppm 22 (%)	4000 ppm 16 (%)
subcutis	edema	5 (19)	6 (29)	2 (9)	0 (0)
	mass	0 (0)	1 (5)	0 (0)	2 (13)
lung	red zone	0 (0)	0 (0)	1 (5)	0 (0)
	nodule	0 (0)	0 (0)	2 (9)	1 (6)
lymph node	enlarged	8 (31)	5 (24)	1 (5)	1 (6)
thymus	cnlarged	1 (4)	0 (0)	0 (0)	0 (0)
spleen	enlarged	3 (12)	5 (24)	3 (14)	1 (6)
	nodule	1 (4)	0 (0)	0 (0)	0 (0)
forestomach	ulcer	1 (4)	0 (0)	0 (0)	0 (0)
small intes	nodule	1 (4)	1 (5)	0 (0)	0 (0)
	dilated	0 (0)	1 (5)	0 (0)	0 (0)
cecum	nodule	0 (0)	1 (5)	0 (0)	0 (0)
liver	enlarged	4 (15)	4 (19)	3 (14)	3 (19)
	white zone	5 (19)	5 (24)	3 (14)	2 (-13)
	red zone	2 (8)	0 (0)	0 (0)	2 (13)
	brown zone	0 (0)	1 (5)	0 (0)	0 (0)
	nodule	5 (19)	8 (38)	13 (59)	8 (50)
	rough	1 (4)	0 (0)	0 (0)	0 (0)
	nodular	1 (4)	0 (0)	0 (0)	0 (0)
kidney	enlarged	0 (0)	1 (5)	2 (9)	0 (0)
	atrophic	0 (0)	1 (5)	0 (0)	0 (0)
	nodule	1 (4)	0 (0)	0 (0)	0 (0)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE

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

)rgan	Findings	Group Name Control NO. of Animals 26 (%)	1000 ppm 21 (%)	2000 ppm 22 (%)	4000 ppm 16 (%)
kidney	hydronophrosis	0 (0)	4 (19)	7 (32)	5 (31)
ıreter	dilated	0 (0)	0 (0)	1 (5)	0 (0)
	thick	0 (0)	0 (0)	1 (5)	0 (0)
urin bladd	urine:marked retention	1 (4)	0 (0)	0 (0)	0 (0)
pituitary	enlarged	2 (8)	1 (5)	0 (0)	1 (6)
	red	1 (4)	0 (0)	0 (0)	0 (0)
ovary	enlarged	5 (19)	6 (29)	4 (18)	1 (6)
	cyst	5 (19)	3 (14)	1 (5)	0 (0)
uterus	nodule	7 (27)	11 (52)	9 (41)	5 (31)
	dilated lumen	1 (4)	0 (0)	0 (0)	0 (0)
llarder gl	enlarged	1 (4)	1 (5)	i (5)	1 (6)
	nodule	0 (0)	0 (0)	1 (5)	1 (6)
Zymbal gl	nodule	1 (4)	0 (0)	0 (0)	0 (0)
mediastinum	mass	4 (15)	3 (14)	0 (0)	0 (0)
peritoneum	nodule	0 (0)	0 (0)	1 (5)	0 (0)
	thick	3 (12)	1 (5)	0 (0)	0 (0)
abdominal c	hemorrhage	2 (8)	2 (10)	3 (14)	0 (0)
	ascites	8 (31)	5 (24)	4 (18)	2 (13)
thoracic ca	hemorrhage	1 (4)	0 (0)	1 (5)	0 (0)
	mass	1 (4)	0 (0)	0 (0)	0 (0)
	pleural fluid	11 (42)		1 (5)	1 (6)
other	forelimb:nodule	0 (0)	0 (0)	I (5)	0 (0)

ANIMAL : MOUSE Crj:BDF1

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

Organ	Findings	Group Name NO. of Animals	Control 26 (%)	1000 ppm 21 (%)	2000 ppm 22 (%)	4000 ppm 16 (%)
ther	lower jaw:nodule		0 (0)	0 (0)	0 (0)	1 (6)
hole body	anemic		1 (4)	0 (0)	0 (0)	0 (0)

APPENDIX J 1

ORGAN WEIGHT, ABSOLUTE: SUMMARY, MOUSE: MALE

ANIMAL : MOUSE Crj:BDF1

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

PAGE: 1

oup Name	NO. of Animals	Body Weight	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS
Control	37	48.1± 7.0	0.011± 0.003	0.219± 0.044	0. 232± 0. 026	0.238± 0.091	0.964± 1.964
500 ppm	38	40.3± 5.3 * *	0.010± 0.003	0.221± 0.051	0.216± 0.018**	0. 222± 0. 046	0.757± 0.893
1000 ppm	42	35.1± 4.1**	0.010± 0.003	0.204± 0.033	0.210± 0.019**	0.208± 0.037*	0.675± 0.447*
2000 ppm	39	31.0± 2.6**	0.009± 0.003	0.209± 0.030	0.197± 0.021**	0.195± 0.027**	0.765± 0.918

(IICL040)

BAIS 4

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1
SEX : MALE

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

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN	
Control	37	0.092± 0.080	1.792± 0.601	0.453± 0.017	
500 ppm	38	0.143± 0.210	1.902± 0.633	0.456± 0.017	
1000 ppm	42	0.169± 0.271	2.092± 0.964	0.453± 0.020	
2000 ppm	39	0.092± 0.112	1.872± 0.504	0.453± 0.018	
Significan	t difference ;	*: P ≤ 0.05 **	: P ≤ 0.01	Test of Dunnett	
(IICL040)	t difference.	+ · ; ≥ 0.00 ++	. 1 = 0.01		

APPENDIX J 2

ORGAN WEIGHT, ABSOLUTE: SUMMARY, MOUSE: FEMALE

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

STUDY NO. : 0372

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

PAGE: 3 UNIT: g

up Name	NO. of Animals	Body Weight	ADRENALS	OVAR	IES	HEART		LUNGS		KIDNI	YS
Control	24	31.1± 3.4	0.013± 0.0	0. 097±	0. 113	0.183±	0. 026	0.249±	0. 243	0.501±	0. 273
1000 ppm	29	28.4± 4.4	0.013± 0.0	0.268±	0.866	0.169±	0.031	0. 197±	0. 053	1.056±	2. 744.
2000 ppm	28	26.4生 5.6**	0.012± 0.6	0.052±	0.077	0. 158±	0.032**	0.191生	0.028	2.107±	6.004
4000 ppm	34	21.5± 2.1**	0.010± 0.0	0.041±	0.037	0.139±	0. 025**	0.173±	0.024**	0.442±	0. 338**

(HCL040)

BAIS 4

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE

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

roup Name	NO. of Animals	SPLEEN		LIVE	ER	BRA	V	
Control	24	0.169± 0.1	159	1.490±	0.300	0.471±	0.021	
1000 ppm	29	0.298± 0.6	572	1.580±	0. 437	0.466±	0.017	
2000 ppm	28	0.168± 0.1	128	1.993±	1.208	0.455±	0.025*	
4000 ppm	34	0.115± 0.1	178**	2.024±	0.976	0.443±	0.021**	
Significan	t difference ;	*: P ≤ 0.05	** :	P ≤ 0.01			Test of Dunnett	
(IICL040)				·				BAIS 4

APPENDIX K 1

ORGAN WEIGHT, RELATIVE: SUMMARY, MOUSE: MALE

(2-YEAR STUDY)

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

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

PAGE: 1

oup Name	NO. of Animals	Body Weight (g)	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS
Control	37	48.1± 7.0	0.023± 0.009	0.461± 0.094	0.495± 0.111	0.504± 0.196	2.119± 4.555
500 ррт	38	40.3± 5.3**	0.025± 0.008	0.557 ± 0.156*	0.547± 0.094*	0.556± 0.114*	1.925± 2.408*
1000 ppm	42	35.1± 4.1**	0.030± 0.009**	0.586± 0.102**	0.602± 0.065**	0.600± 0.127**	1.932± 1.234**
2000 ppm	39	31.0± 2.6**	0.031± 0.011**	0.679± 0.109**	0.639± 0.068**	0.637± 0.128 **	2. 473± 2. 930**

(IICL042)

BAIS 4

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1
SEX : MALE
UNIT: %

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

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN	
Control	37	0.199± 0.171	3.919± 2.259	0.967± 0.173	
500 ppm	38	0.373± 0.584*	4.945± 2.625**	1.151± 0.157**	
1000 ppm	42	0.506± 0.867**	6.162± 3.224**	1.308± 0.156**	
2000 ppm	39	0.298± 0.365*	6.115± 1.984**	1. 470 ± 0. 127**	
Significan	t difference ;	* : P ≤ 0.05 **:	P ≤ 0.01	Test of Dunnett	
(1101.040)					DATC A

(IICL042)

BAIS 4

APPENDIX K 2

ORGAN WEIGHT, RELATIVE: SUMMARY, MOUSE: FEMALE

(2-YEAR STUDY)

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE UNIT: % ORGAN WEIGHT: RELATIVE (SUMMARY)

SURVIVAL ANIMALS (105W)

PAGE: 3

Group Name	NO. of Animals	Body Weight (g)	ADRENALS	OVARIES	HEART	LUNGS	KIDNEYS
Control	24	31. 1± 3. 4	0.040± 0.009	0. 310± 0. 383	$0.600\pm\ 0.129$	0. 831± 0. 904	1. 655± 0. 992
1000 ppm	29	28. 4± 4. 4	0. 045± 0. 018	0.893± 2.780	0.597± 0.086	0.700± 0.187	3. 077± 6. 025*
2000 ppm	28	26.4± 5.6**	0. 046± 0. 009	0. 201± 0. 268	0.612± 0.136	0.745± 0.157*	5. 634±12. 482**
4000 ppm	34	21.5± 2.1**	0.049± 0.015*	0. 193± 0. 198	0.649± 0.122	0.810± 0.100**	2. 070± 1. 574**
Significan	t difference ;	* : P ≤ 0.05 **	: P ≤ 0.01	Tes	t of Dunnett		

(HCL042)

BAIS4

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE UNIT: % ORGAN WEIGHT: RELATIVE (SUMMARY)

SURVIVAL ANIMALS (105W)

PAGE: 4

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN	
Control	24	0. 576± 0. 598	4. 891± 1. 346	1. 533± 0. 186	
1000 ppm	29	1. 048± 2. 384	5. 611± 1. 529	1. 674± 0. 231	
2000 ppm	28	0. 642± 0. 487	7.834± 5.039**	1. 775± 0. 254**	
4000 ppm	34	0.510± 0.734	9. 451± 4. 632**	2. 081± 0. 225**	
Significan	t difference ;	* : P ≤ 0.05 **	$P \leq 0.01$	Test of Dunnett	

(HCL042)

BAIS4

APPENDIX L 1

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOUSE: MALE: ALL ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

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

REPORT TYPE : A1

SEX : MALE

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

rgan	Findings	Group Name No. of Animals on Study Grade(%)	50 2	3 (%)	<u>4</u> (%)	1 (%)	50 5 2 (%)	0 ppm 0 3 (%)	4 (%)	1(%)	2	3 (%)	<u>4</u> (%)	<u>1</u> (%)		00 ppm 50 3 (%)	<u>4</u> (%)
lntegumentary	system/appandage}																
kin/app	ulcer	0 (0)	<50. 0 (0) (0	0	1 (2)	<5 1 (2)	0	0 (0)	0 (0)		0 0) (0 0)	1 (2)	2	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)	1 (2)	0 (0)
Respiratory s	system}																
asal cavit	eosinophilic change:olfactory epith		<500 1 (2) (0	0 (0)	11 (22)	<5 0 (0)	0	0 (0)	22 (44)		0 0) (0 0)	23 (46)	I	0 (0)	0
	eosinophilic change:respiratory epi		0 (0) (1 2)	0 (0)	25 (50)	1 (2)	1 (2)	0 (0)	25 (50)		0 0) (0 0)	36 (72)	6 (12)	3 (6)	0 : (0)
	respiratory metaplasia:olfactory ep		0 (0) (0	0 (0)	7 (14)	0 (0)	0 (0)	0 * (0)	12 (24)	(2	0 0) (0 0)	11 (22)	0 (0)	0 (0)	0 (0)
	respiratory metaplasia:gland	28 (56)	3 (6) (0	0 (0)	22 (44)	3 (6)	0 (0)	0 (0)	22 (44)		0 0) (0 0)	34 (68)	0 (0)	0 (0)	0 (0)
	inflammation:transitional epithelium	-	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)

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : MOUSE Crj:BDF1 ALL ANIMALS (0-105W)

STUDY NO. : 0372 ANIMAL : MOUSE REPORT TYPE : A1

SEX : MALE

Organ	Findings	Group Name No. of Animals on Study Grade 1 (%)	Control 50 2 3 4 %) (%) (%)	500 ppm 50 1 2 3 4 (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)
Respiratory s	system)					
asopharynx	eosinophilic change		<50> 0 0 0 0) (0) (0)	<50> 1 1 0 0 (2) (2) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)	<50> 4 0 0 0 (8) (0) (0) (0)
trachea	eosinophilic change		<50> 0 0 0 0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	\(\langle 50 \rangle \) \[1 1 0 0 \\ (2) (0) (0) \]
ung	congestion	0 (0) (<50> 0 0 0 0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
	hemorrhage	0 (0) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 (0) (0)	3 0 0 0 0 (6) (6) (0) (0)	0 0 0 0 0 (0) (0)
	edema	1 (2) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (0)
	inflammatory infiltration	2 (4) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	1 0 0 0 0 (2) (0) (0) (0)	1 0 0 0 0 (2) (0) (0)	3 0 0 0 0
	granulation	0 (0) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 (0) (0)	0 0 1 0 (0) (2) (0)	0 0 0 0 0 (0) (0) (0)

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

(HPT150)

BAIS4

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

b : Number of animals with lesion

⁽c) c:b/a * 100

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

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1

Organ	Findings	Group Name No. of Animals on Study Grade	2		>1 3 %)	<u>4</u> (%)		<u>1</u> (%)			pm 3 4 %) (%)	1 (%)		1000 50 2 %)		<u>4</u> (%)	(%	<u>1</u> %)		00 ppr 50 3 (%)	 <u>4</u> (%)
Respiratory :	system)												İ				-				
lung	accumulation of foamy cells	2 (4			0 0) (0 (0)	(0	0		0 0	1 (2)		<50: 0 0) (0	0 (0)		1 2) (1	50> 0 (0)	0
	bronchiolar cell hyperplasia	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
	bronchiolar-alveolar cell hyperplasia		: 0 () (0)		0 0) (0 (0)		15 30)	0 (0)		0 0	15 (30)		0 0) (0 0)	0 (0)	(3		0 0)	(0	0
(Hematopoieti	c system)																				
one marrow	thrombus		0 0) (0)		0 0) (0 (0)	(0	0	(50>	0 0	0 (0)		<50 0 0) (0	0 (0)		1 2) (0	50> 0 (0	0
	decreased hematopoiesis) 1) (0 0) (0	(0	(0)		0 0	(2)		0 0) (0	0 (0)		0 0) (0 0)	(0	0
	myelofibrosis	1	i 0		0 0) (0 (0)	(1 2)	0 (0)		0 0 0) (0)	1 (2)		0 0) (0 0)	0 (0)		1 2) (0	0 (0	0
	erythropoiesis:increased	(2	l 0 2) (0,		0 0) (0 (0)	(3 6)	(0)		0 0	1 (2)		0 0) (0 0)	0 (0)	(i 2) (0 0)	0 (0	0

Grade

a : Number of animals examined at the site

b : Number of animals with lesion

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

(HPT150)

BATS4

< a >

b

c:b/a*100 (c)

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

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

REPORT TYPE : A1

Organ	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	500 ррт 50 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)
llematopoieti	c system)				
one marrow	megakaryocyte:increased	<50> 2 0 0 0 (4) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
pleen	deposit of hemosiderin	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	2 0 0 0 (4) (0) (0) (0)
	deposit of melanin	2 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 (0) (0)	2 0 0 0 0 (4) (0) (0) (0)	0 0 0 0
	plasma cell hyperplasia	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)
	extramedullary hematopoiesis	5 1 5 0 (10) (2) (10) (0)	5 3 4 0 (10) (6) (8) (0)	10 4 2 0 (20) (8) (4) (0)	12 2 1 0 (24) (4) (2) (0)
	hyperplasia:mast cell	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (2) (0) (0)	0 0 0 0 0 (0) (0)
	follicular hyperplasia	1 0 0 0 0 (2) (0) (0) (0)	2 1 0 0 (4) (2) (0) (0)	2 1 0 0 (4) (2) (0) (0)	0 0 0 0 0
Circulatory	system)				
eart	thrombus	(0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 1 0 (0) (0) (2) (0)

< a > b

a : Number of animals examined at the site

b : Number of animals with lesion (c) с: b / a * 100

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

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE

Organ	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 (%) (%) (%)	500 ppm 50 4 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)
Circulator	y system)				
eart	mineralization	<50> 0 0 0 (0) (0) (0) (0 1 0 0 0 0) (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
	granulation	0 0 0 0 (0) (0) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	1 0 0 0 0 (2) (0) (0)	0 0 0 0 0 (0)
	arteritis	1 0 0 (2) (0) (0) (0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 (0)	0 0 0 0 0
	dilatation:right ventricle	2 0 0 (4) (0) (0) (0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	1 0 0 0 0 (2) (0) (0)	1 0 0 0 0 (2) (0) (0)
Digestive	system)			·	
ooth	dysplasia	<50> 0 0 0 (0) (0) (0) (0 0 0 1 0 0) (0) (0) (2) (0)	<pre></pre>	<50> 0 0 0 0 (0) (0) (0) (0)
ongue	arteritis	<50> 0 0 0 (0) (0) (0) (0 0 0 0 0 0) (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)
Grade < a > b (c) Significan	1: Slight 2: Moderate a: Number of animals examined at t b: Number of animals with lesion c: b/a*100 t difference; *: P ≤ 0.05 **:	3: Marked 4: Severe lie site $P \leq 0.01 \text{Test of Chi Square}$			

(IIPT150)

BAIS4

PAGE: 6

BAIS4

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

SEX : MALE

rgan	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	500 ppm 50 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)
Digestive sy	stem)				
alivary gl	atrophy	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)
	inflammatory infiltration	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	fibrosis:focal	0 0 0 0 0 (0) (0)	0 0 0 0 0	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)
stomach	mineralization	<50> 3 0 0 0 (6) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
	inflammatory infiltration	5 0 0 0 (10) (0) (0) (0)	0 0 0 0 0 (0) (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 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0)
	hyperplasia:forestomach	0 0 0 0 0 (0) (0)	0 0 0 0 0	1 0 0 0 0 (2) (0) (0) (0)	2 0 0 0 0 (4) (0) (0) (0)
	erosion:glandular stomach	2 0 0 0 (4) (0) (0) (0)	0 0 0 0 0	2 0 0 0 0 (4) (0) (0) (0)	0 0 0 0

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

STUDY NO. : 0372

: MOUSE Crj:BDF1 ANIMAL

REPORT TYPE : A1 : MALE

2000 ррт 1000 ppm 500 ppm Group Name Control 50 50 50 No. of Animals on Study (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) Findings_ Organ____

{Digestive sys	stem)				
stomach	ulcer:glandular stomach	(0) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)
	hyperplasia:glandular stomach	6 0 1 0 (12) (0) (2) (0)	1 0 0 0 (2) (0) (0) (0)	0 0 0 0 *	1 0 0 0 0 (2) (0) (0) (0)
	ectopia:glandular stomach	2 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0)
liver	congestion	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	<pre></pre>	(0) (0) (0) (0)
	angiectasis	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0)
	necrosis:central	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	1 0 0 0 (2) (0) (0)	0 2 0 0 (0) (0) (0)
	necrosis:focal	1 1 0 0 (2) (2) (0) (0)	2 0 0 0 0 (4) (0) (0) (0)	3 0 0 0 0	3 1 0 0 (6) (2) (0) (0)
	necrosis:single cell	3 0 0 0 0 (6) (6) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0)

Grade

2 : Moderate

3 : Marked

4 : Severe

(a)

1 : Slight

a : Number of animals examined at the site

(c)

b : Number of animals with lesion

c:b/a*100

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

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE

Organ	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	500 ppm 50 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)
Digestive	system)				
iver	fatty change	<50> 1 0 0 0 (2) (0) (0) (0)	<pre></pre>	<50> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>
	fatty chango:central	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0
	degeneration:focal	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0
	inflammatory infiltration	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0
	lymphocytic infiltration	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0
	granulation	30 0 0 0 0 (60) (31 0 0 0 0 (62) (0) (0) (0)	27 2 0 0 (54) (4) (0) (0)	26 0 0 0 (52) (0) (0) (0
	extramedullary hematopoicsis	0 0 0 0 0 (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	1 0 0 0 0 (2) (0) (0)	0 0 0 0 0 0 (0) (0) (0
	clear cell focus	3 0 0 0 0 (6) (6) (70) (70)	6 0 0 0 (12) (0) (0) (0)	1 1 0 0 (2) (2) (0) (0)	0 0 0 0

Grade

^{1 :} Slight

^{2 :} Moderate

^{3 :} Marked

^{1 :} Severe

< a >

a: Number of animals examined at the site

b

b: Number of animals with lesion

⁽c) c:b/a*100

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

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE

rgan	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	500 ppm 50 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)
Digestive sys	stem)				
iver	acidophilic cell focus	<50> 1 1 0 0 (2) (2) (0) (0)	<pre></pre>	<50> 5 4 0 0 (10) (8) (0) (0)	500 0 0 0 (10) (0) (0) (0)
	basophilic cell focus	2 0 0 0 (4) (0) (0) (0)	5 0 0 0 (10) (0) (0) (0)	6 3 0 0 (12) (6) (0) (0)	7 1 1 0 (14) (2) (2) (0)
	mixed cell focus	0 0 0 0 0	0 0 0 0 0	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0
	bile ductular proliferation	0 0 0 0 0 (0) (0)	2 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 (0)	1 0 0 0 0 (2) (0) (0) (0)
	biliary cyst	3 0 0 0 0 (6) (6) (7)	3 0 0 0 0 (6) (6) (0) (0)	3 0 0 0 0 (6) (6) (7)	1 0 0 0 0 (2) (0) (0)
	focal fatty change	2 0 0 0 (4) (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0)	0 0 0 0 0 (0) (0)
gall bladd	cyst	<46> 0 0 0 0 0 0 0 0 0 0 0	(50) 1 0 0 0 (2) (0) (0) (0)	<pre></pre>	0 0 0 0 (0) (0) (0) (0)
	eosinophilic change	3 0 0 0 (7) (0) (0) (0)	2 0 0 0 0 (4) (0) (0) (0)	3 1 0 0 (6) (2) (0) (0)	0 1 0 0 (0) (0)

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

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

SEX : MALE

Organ	Findings	Group Name Control No. of Animals on Study .50 Grade 1 2 3 4 (%) (%) (%)	500 ppm 50 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)
(Digestive sys	tem)				
gall bladd	hyperplasia	(46) 0 0 0 0 (0)(0)(0)(0)	<pre></pre>	\$ 0 0 0 * (16) (0) (0) (0)	<47> 8 0 0 0 ** (17) (0) (0) (0)
pancreas	atrophy	<50> 0 1 0 0 (0) (2) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
{Urinary syst	em)				(50)
kidney	hemorrhage	<50> 1 0 0 0 (2) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)
	infarct	0 0 0 0 0 (0)	1 0 0 0 0 (2) (0) (0)	1 0 0 0 0 (2) (0) (0)	0 0 0 0 0 0 (0) (0)
	cyst	1 1 0 0 (2) (2) (0) (0)	1 1 0 0 (2) (2) (0) (0)	1 0 0 0 0 (2) (0) (0)	0 0 0 0 0 (0) (0)
	hyaline droplet	1 2 0 0 (2) (4) (0) (0)	2 0 0 0 0 (4) (0) (0) (0)	2 1 0 0 (4) (2) (0) (0)	3 0 0 0 0 (6) (6) (7)

 $\overline{}$

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

(HPT150)

BA1S4

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

100

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE

500 ppm 1000 ppm 2000 ррш Control Group Name 50 50 50 50 No. of Animals on Study Grade (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) Findings_ Organ_ (Urinary system) <50> <50> <50> <50> kidney 0 0 0 0 0 0 0 0 0 0 39 basophilic change (78) (0) (0) (0) (80) (0) (0) (0) (68) (0) (0) (0) (80) (0) (0) (0) 0 0 0 0 0 0 deposit of hemosiderin (2)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) 0 1 0 1 0 0 0 inflammation (0) (0) (0) (0) (0)(0)(0)(0) (2)(0)(0)(0) (0)(2)(0)(0) 4 1 3 0 0 0 4 0 0 0 lymphocytic infiltration (8)(2)(0)(0) (16) (0) (0) (0) (8)(0)(0)(0) (6)(0)(0)(0) 2 0 0 0 2 0 0 inflammatory polyp (0)(2)(2)(0) (0)(2)(4)(0) (0)(0)(4)(0) (0)(4)(0)(0) 0 0 1 1 0 0 3 1 0 2 1 0 hydronephrosis (0)(0)(4)(0) (0)(0)(6)(2) (0)(0)(2)(2) (0)(4)(2)(0) 0 1 0 0 0 0 0 0 0 mineralization:pelvis (0)(0)(0)(0) (0)(0)(0)(0) (2)(0)(0)(0) (2)(0)(0)(0) 0 0 19 0 0 0 mineralization:cortex 0 0 13 0 (20) (0) (0) (0) (22) (0) (0) (0) (26) (0) (0) (0) (38) (0) (0) (0)

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

b : Number of animals with lesion

(c) c:b/a*100

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

(HPT150)

BAIS4

STUDY NO. : 0372

: MOUSE Crj:BDF1

REPORT TYPE : A1

ANIMAL

: MALE

2000 руш 500 ppm 1000 ррт Control Group Name 50 50 50 50 No. of Animals on Study 3 3 Grade (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) Findings_ Organ_ (Urinary system) <50> <50> <50> <50> kidney 0 0 0 0 0 0 0 0 0 0 0 0 glomerulosclerosis (0)(0)(2)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) <50> <50> <50> <50> urin bladd 0 0 1 0 0 0 2 0 0 0 3 0 0 0 0 0 dilatation (0)(0)(2)(0) (0)(0)(4)(0) (0)(0)(6)(0) (0)(0)(0)(0) 0 0 1 0 0 0 0 inflammation (0)(0)(0)(0) (0)(0)(0)(0) (2)(0)(0)(0) (0)(0)(0)(0) (Endocrine system) <49> <48> <50> pituitary 0 0 0 0 0 0 2 cyst (4)(0)(0)(0) (2)(0)(0)(0) (2)(0)(0)(0) (4)(0)(0)(0) 0 0 0 0 0 1 0 0 1 0 0 0 hyperplasia (6)(0)(0)(0) (0) (0) (0) (0) (0)(2)(0)(0) (2)(0)(0)(0) 3 0 0 0 0 0 0 4 0 0 0 3 0 0 Rathke pouch (0)(0)(0)(0) (8) (0) (0) (0) (6)(0)(0)(0) (6)(0)(0)(0)

 $\widetilde{\mathcal{L}}$

Grade

^{1 :} Slight

^{2 :} Moderate

^{3 :} Marked

^{4 :} Severe

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

b b: Number of animals with lesion

⁽c) c:b/a * 100

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

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BAIS4

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1
SEX : MALE

)rgali	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	500 ppm 50 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)
Endocrine sy	ystem) lymphocytic infiltration	<49> 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
	ultimibranchial body remanet	0 0 0 0 0 (0) (0)	1 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0
	C-cell hyperplasia	3 0 0 0 0	3 0 0 0 0 (6) (6) (0) (0)	0 0 0 0 0 (0) (0) (0)	1 0 0 0 (2) (0) (0)
	cystic thyroid follicle	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	1 0 0 0 0 (2) (0) (0)
adrenal	cyst	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)
	spindle-cell hyperplasia	21 0 0 0 (42) (0) (0) (0)	18 2 0 0 (36) (4) (0) (0)	16 1 0 0 (32) (2) (0) (0)	12 0 0 0 (24) (0) (0) (0)
	hyperplasia:cortical cell	7 i 0 0 (14) (2) (0) (0)	11 4 0 0 (22) (8) (0) (0)	8 0 0 0 0 (16) (0) (0)	5 1 0 0 (10) (2) (0) (0)
{Reproduct	tive system)	(FA)	· <50>	<50≻	<50>
testis	atrophy	<50> 9 0 0 0 (18) (0) (0) (0)	2 0 0 0 0 (4) (0) (0) (0)	12 0 0 0 (24) (0) (0) (0)	10 0 0 0 (20) (0) (0)

^{4 :} Severe 3 : Marked 2 : Moderate 1 : Slight Grade

(HPT150)

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

b : Number of animals with lesion b

c:b/a*100 Significant difference ; * : P \leq 0.05 ** : P \leq 0.01 Test of Chi Square

STUDY NO. : 0372

ANIMAL : MOUSE Cr.j:BDF1

REPORT TYPE : A1 SEX : MALE

1000 ppm 2000 ppm 500 ppm Group Name Control 50 50 No. of Animals on Study 50 Grade (%) (%) (%) (%) (%) (%) (%) (%) Organ_ Findings_ (Reproductive system) <50> <50> <50> <50> testis 0 0 0 1 0 0 0 0 0 46 0 0 0 43 mineralization (90) (0) (0) (0) (86) (2) (0) (0) (96) (0) (0) (0) (92) (0) (0) (0) 0 0 0 interstitial cell hyperplasia 1 0 0 0 0 0 (2)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) 0 0 0 spermatogenic granuloma 0 0 0 0 0 0 0 0 (2)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) <50> <50> <50> <50> epididymis 0 0 0 1 0 0 0 0 0 0 inflammation (0)(0)(0)(0) (2)(0)(0)(0) (0)(0)(0)(0) (4)(0)(0)(0) spermatogenic granuloma (8)(0)(0)(0) (8)(0)(0)(0) (6)(0)(0)(0) (6) (4) (0) (0) 0 1 0 0 0 0 0 0 0 0 xanthogranuloma (0)(0)(0)(0) (2)(0)(0)(0) (0)(0)(0)(0) (0)(0)(2)(0) <50> <50> prep/cli gl <50> <50> 9 0 0 0 0 0 0 2 0 0 0 5 1 0 0 duct ectasia (18) (0) (0) (0) (14) (0) (0) (0) (4)(0)(0)(0) (10) (2) (0) (0)

4 : Severe

Grade

^{1 :} Slight

^{2 :} Moderate

^{3 :} Marked

a: Number of animals examined at the site

⁽a) b: Number of animals with lesion ь

⁽c) c:b/a * 100

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

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

(IIPT150)

REPORT TYPE : A1 SEX : MALE

Organ	No	oup Name	500 pμm 50 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)
Nervous syst	.em}				
orain	mineralization	<50> 21 0 0 0 (42) (0) (0) (0)	<50> 8 0 0 0 ** (16) (0) (0) (0)	<50> 20	<pre></pre>
	gliosis	2 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	3 0 0 0
{Special sens	se organs/appendage)				
еуе	degeneration:cornea	(50) 1 0 0 0 (2) (0) (0) (0)	<50> 1 1 0 0 (2) (2) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)
llarder gl	hyperplasia	(49) 1 0 0 0 (2) (0) (0) (0)	(50) 0 1 0 0 (0) (2) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)
{Body caviti	es)			•	
peritoneum	xanthogranuloma	<pre></pre>	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 1 0 (0) (0) (2) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
Grade <a> b (c) Significant	1: Slight 2: Moderate 3 a: Number of animals examined at the si b: Number of animals with lesion c: b / a * 100 difference; * : P ≤ 0.05 **: P ≤				

APPENDIX L 2

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOUSE: FEMALE: ALL ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0372 ANIMAL : MOUSE

: MOUSE Crj:BDF1

REPORT TYPE : A1

SEX : FEMALE

4000 ppm 2000 ppm 1000 ppm Control Group Name 50 50 50 50 No. of Animals on Study 3 Grade (%) (%) (%) (%) ^ (%) (%) (%) (%) (%) Findings_ (Integumentary system/appandage) <50> <50> skin/app 0 0 0 0 0 0 0 0 1 0 0 0 inflammation (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (2)(0)(0)(0) 0 0 0 1 0 0 scar:dermis (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(2)(0)(0) <50> <50> <50> <50> subcutis 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 hemorrhage (2)(0)(0)(0) (0) (0). (0) (0) (0)(0)(0)(0) (0)(0)(0)(0) {Respiratory system} ⟨50⟩ <50> <50> nasal cavit 0 0 0 0 0 0 0 0 exudate (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (2)(0)(0)(0) 0 0 0 0 0 0 0 1 0 0 0 angiectasis (8)(0)(0)(0) (0)(0)(0)(0) (2)(0)(0)(0) (0)(0)(0)(0) 0 0 0 0 1 0 0 0 0 0 0 0 0 0 0 hemorrhage (0)(0)(0)(0) (2)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0)

4 : Severe

3 : Marked

Grade

< a >

b

(c)

1: Slight

c:b/a*100

2 : Moderate

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

a : Number of animals examined at the site

b: Number of animals with lesion

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)

.___

ALL ANIMALS (0-105W)

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ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1

SEX : FEMALE

STUDY NO. : 0372

Organ	Group No. o Grade Findings	f Animals on Study 50	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
{Respiratory	system)				
nasal cavit	eosinophilic change:olfactory epithelium	<50> 7	(50) 1 0 0 0 (2) (0) (0) (0)	<50> 11 0 0 0 (22) (0) (0) (0)	\(\langle 50 \) 18
	eosinophilic change:respiratory epithelium	30 5 2 0 (60) (10) (4) (0)	26 18 1 0 *** (52) (36) (2) (0)	15 32 1 0 ** (30) (64) (2) (0)	9 28 11 0 *** (18) (56) (22) (0)
	respiratory metaplasia:olfactory epithelium	2 0 0 0 (4) (0) (0) (0)	1 0 0 0 0 (2) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0)
	respiratory metaplasia:gland	14 0 0 0 0 (28) (0) (0) (0)	19 0 0 0 0	22 5 0 0 ** (44) (10) (0) (0)	31 3 0 0 *** (62) (6) (0) (0)
nasopharynx	eosinophilic change	<50> 2 1 0 0 (4) (2) (0) (0)	50> 5 0 0 0 (10) (0) (0) (0)	3 0 0 0 (6) (0) (0) (0)	(50) 13 0 0 0 *** (26) (0) (0) (0)
lung	edema	<50> 0 0 0 0 0 0 0 0 0 0 0	50> 0 0 0 0 0 0 0 0	<pre></pre>	(50) 1 0 0 0 (2) (0) (0) (0)
	inflammatory infiltration	3 0 0 0 (6) (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	3 0 0 0 0 (6) (6) (7)	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; $*: P \le 0.05$ **: $P \le 0.01$ Test of Chi Square

BAIS4

PAGE : 17

(IIPT150)

STUDY NO. : 0372

REPORT TYPE : A1 SEX : FEMALE

ANIMAL : MOUSE Crj:BDF1

Organ	1	From Name Control do. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)		2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
{Respiratory	system]				
lung	lymphocytic infiltration	<50> 0 0 0 0 (0) (0) (0) (0		(49) 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
	accumulation of foamy cells	1 0 0 0 (2) (0) (0) (0		0 0 1 0 (0) (2) (0)	0 0 0 0 0 (0) (0)
	bronchiolar-alveolar cell hyperplasia	6 0 0 (7 0 0 0 (14) (0) (0) (0)	13 0 0 0 (26) (0) (0) (0)
{Hematopoiet	ic system)				
oone marrow	decreased hematopoiesis	(50) 1 0 0 (2) (0) (0) ((50) 0 0 0 0 0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)
	myelofibrosis	4 0 0 (8) (0) (0) ((8) (0) (2) (0)	3 1 0 0 (6) (2) (0) (0)	2 0 0 0 0 (4) (0) (0)
	mogakaryocyto:increased	1 0 0 (2) (0) (0) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 (0) (0)	4 0 0 0 0 (8) (0) (0) (0)
	granulopoiesis:increased	0 1 0 (0) (2) (0) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	1 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)

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

ь b : Number of animals with lesion

(c) c:b/a*100

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

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1

SEX : FEMALE

STUDY NO. : 0372

Organ	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
{ ematopoieti	c system)				
lymph node	lymphadenitis	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
spleen	atrophy	(50) 0 0 0 0 (0) (0) (0) (0)	(50) (0) (0) (0) (0)	<50> 2	(50) 2
	angiectasis	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	deposit of hemosiderin	2 0 0 0 (4) (0) (0) (0)	8 0 0 0 0 (16) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	3 0 0 0 0
	deposit of melanin	2 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 (0)	2 0 0 0 0 (4) (0) (0) (0)	5 0 0 0 (10) (0) (0) (0)
	extramedullary hematopoiesis	14 5 1 0 (28) (10) (2) (0)	5 1 1 0 * (10) (2) (2) (0)	10 7 2 0 (20) (14) (4) (0)	9 2 4 0 (18) (4) (8) (0)
	follicular hyperplasia	0 0 0 0 0 (0) (0)	1 0 0 0 (8) (0) (0) (0)	1 2 0 0 (2) (4) (0) (0)	2 1 0 0 (4) (2) (0) (0)
{Circulatory	y system)				
heart	thrombus	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	(50) (0) (0) (0) (0)

1 : Slight Grade

2 : Moderate

3 : Marked

4 : Severe

< a >

a: Number of animals examined at the site

b: Number of animals with lesion b

c:b/a*100 (c)

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

(HPT150)

BAIS4

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

 \searrow

STUDY NO. : 0372 ANIMAL : MOUSE Cr.j:BDF1
REPORT TYPE : A1
SEX : FEMALE

rgan	No	oup Name Control . of Animals on Study 50 ade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%) (%)
Circulatory	/ system]				
eart	mineralization	(50) 1 0 0 0 (2) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	<50> 0 0 0 0 (0) (0) (0) (0)
	myocardial fibrosis	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 0 (0) (0)
	arteritis	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0	0 0 0 0 0 0 (0)	0 0 0 0 0 (0) (0)
	dilatation:right ventricle	2 0 0 0 0 (4) (0) (0) (0)	1 0 0 0 0 (2) (0) (0)	0 0 0 0 0 (0) (0)	2 0 0 0 0 (4) (0) (0) (0)
Digestive	system)				
ooth	inflammation	<50> 0 0 0 0 0 0 0 0 0 0 0	<50> 0 0 0 0 0 0 0 0 0 0 0	<50> 0 1 0 0 (0) (2) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
stomach	inflammatory infiltration	<50> 0 0 0 0 0 0 0 0 0 0 0	(50) 1 0 0 0 (2) (0) (0) (0)	(50) 1 1 0 0 (2) (2) (0) (0)	<pre></pre>
Grade (a) b (c)	1: Slight 2: Moderate 3: a: Number of animals examined at the sit b: Number of animals with lesion c: b / a * 100 t difference; *: P ≤ 0.05 **: P ≤				

PAGE: 21

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

SEX : FEMALE

rgan	Findings	Group Name No. of Animals on Study Grade 1 (%)	Con 50 2) (%)		<u>4</u> (%)	-	1 %)	1000 50 2 (%)	3 (%)	<u>4</u> (%)	<u> </u>	<u>l</u> 6)	200 5 2 (%)	0 ppm 0 3 (%)		<u>4</u> (%)	<u> </u>	5)		3	<u>4</u> (%)
Digestive s	system)																				
tomach	ulcer:forestomach	1 (2)	<50 0) (0) (0	0 (0)		0 0) (<54 1 2)		0 (0)		0 0) (0	50> 0 (0)		0) (0)	0	0 0) (0
	hyperplasia:forestomach	2 (4)	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
	erosion:glandular stomach	1 (2)	0	0 (0)	0 (0)	(I 2)	0 (0)	0 (0)	0 (0)		0 0) (0 (0)	0		0		0 0) (0 (0)	0 0) (0
	ulcer:glandular stomach	2 (4)	2 0	0 (0)	0 (0)		0	0 (0)	0 (0)	0 (0)		0	0	(0		0		0 0) (0	0 0) (((
mall intes	ulcer	0 (0)	<50 0 1 0) (2)	0	0 (0)) (0	0	0 (0)	0 (0)	(0 0)	0	50> (())) (0 0)		0 0) (0	0	((
iver	angiectasis		<5 2 3 4) (6)	0	0 (0		0	0		0 (0)	(0	0	:50> (((0 0)		0	0	0	((
	necrosis:focal		1 1 2) (2)	0 (0)	0) (1 2)	1 (2)	0 (0)	0 (0)	(1 2)	0 (0)	(0 0) (0 0)	(1 2)	0	0	(

^{1 :} Slight 2 : Moderate 3 : Marked 4 : Severe Grade

(IIPT150)

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

⁽c) c:b/a*100

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

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

SEX : FEMALE

rgan	Findings	Group Name No. of Animals on Study Grade 1 (%)	Con 50 2 (%)		<u>4</u> (%)	1 (%)		00 ppr 50 3 (%)	4		<u>1</u> (%)		(%)	4		1 (%)		400 5 2 (%)	1q 00 00 8)	3	(%)
Digestive	system)																				
liver	necrosis:single cell	1 (2)	<50 0 (0) (0	0 (0)	0 (0)	0		0 (0)	(0	0	50> 0 (0)	0 (0)	(0 0)	(0		0 0) (0 (0)
	fatty change	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)
	degeneration:focal	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	((0 0) (0)	(i 2)	0 (0)	(0	0 (0)	(0) (0 0)		0 0)	0 (0)
	atrophy:focal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	(2)	(0 (0)	(0 0)	0 (0)	0	0	(0) (0 0)	(0	(0
	inflammatory infiltration	2 (4)	0 (0)	0 (0)	0 (0)	1 (2)	(0)) ((0 0	(0	0 (0)		0 0	(0		0 0)		0 0)	(0
	lymphocytic infiltration	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	(0) (0 0	(2 4)	0 (0)		0 0	•	(0)) (0		0	(0
	granulation	9 (18)	1 (2)	0 (0)	0 (0)	8 (16)	(0		0 0	(3 6)	0) ((0) (0)		13 (20		0 0)		0 0)	(0
	inflammatory cell nest	17 (34)	0	0 (0)	0 (0)	16 (32)	0 (0		0 0	(20 40)	(0) (0 0) 3) (0 (0)		0	((

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

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

b: Number of animals with lesion b

c:b/a*100 (c)

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

STUDY NO. : 0372

ANIMAL : MOUSE Cr j: BDF1

SEX : FEMALE

REPORT TYPE : A1

rgan	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
Digestive sys	tem)				
iver	extramedullary hematopoiesis	3 0 0 0 (6) (0) (0) (0)	<50> 6 0 0 0 (12) (0) (0) (0)	50> 5 0 0 0 (10) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
	clear cell focus	0 0 0 0 0 (0) (0)	4 0 0 0 0 (8) (0) (0)	3 0 0 0 0 (6) (6) (0) (0)	6 0 2 0 * (12) (0) (4) (0)
	acidophilic cell focus	1 0 0 1 (2) (0) (0) (2)	3 1 0 0 (6) (2) (0) (0)	3 0 0 0 0 (6) (6) (7)	12 5 1 0 * (24) (10) (2) (0)
	basophilic cell focus	0 1 0 0 (0) (2) (0) (0)	5 2 0 0 (10) (4) (0) (0)	4 0 0 0 0 (8) (0) (0) (0)	9 1 0 0 *
	bile ductular proliferation	2 0 0 0 (4) (0) (0) (0)	4 0 0 0 0 (8) (0) (0) (0)	8 0 0 0 0 (16) (0) (0)	4 0 0 0 0 (8) (0) (0)
	biliary cyst	3 1 0 0 (6) (2) (0) (0)	7 0 1 0 (14) (0) (2) (0)	5 0 0 0 0 (10) (10) (10)	3 0 0 0 0
	focal fatty change	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0	0 0 0 0 0 (0)
gall bladd	dilatation	<47> 0 0 0 0 0 0 0 0 0	<47> 0 1 0 0 (0) (2) (0) (0)	<49> 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<45> 0 0 0 0 0 0 0 0 0 0 0

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

b b: Number of animals with lesion

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

BAIS4

STUDY NO. : 0372

: MOUSE Crj:BDF1 ANIMAL

REPORT TYPE : A1 SEX : FEMALE

Organ	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
{Digestive sy	rstem)				
gali bladd	eosinophilic change	2 0 0 0 0 (4) (0) (0) (0)	2 2 0 0 (4) (4) (0) (0)	3 0 0 0 (6) (0) (0) (0)	(45) 0 1 0 0 (0) (2) (0) (0)
	hyperplasia	0 0 0 0 0 (0) (0)	2 0 0 0 0 (4) (0) (0)	14 0 0 0 *** (29) (0) (0) (0)	10 0 0 0 *** (22) (0) (0) (0)
{Urinary sys	tem}				
kidney	infarct	(50) 1	(50) 1 0 0 0 (2) (0) (0) (0)	<50> 2 0 0 0 (4) (0) (0) (0)	<50> 4 2 0 0 (8) (4) (0) (0)
	cyst	0 0 0 0 0 (0) (0)	0 0 1 0 (0) (2) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)
	hyaline droplet	5 5 0 0 (10) (10) (0) (0)	5 8 2 0 (10) (16) (4) (0)	8 4 0 0 (16) (8) (0) (0)	3 5 0 0 (6) (10) (0) (0)
	basophilic change	11 0 0 0 (22) (0) (0) (0)	16 1 0 0 (32) (2) (0) (0)	9 1 0 0 (18) (2) (0) (0)	18 0 0 0 0
	deposit of hemosiderin	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) (0)

Grade

1 : Slight

2 : Moderate

3 : Marked

4 : Severe

(a)

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

b (c)

c:b/a*100

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

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE

Organ	Findings	Group Name No. of Animals on Study Grade 1 (%)	Con 50 2 (%)	(%)	<u>4</u> (%)	1 (%)		00 pp 50 3 (%		-	<u>1</u> (%)		0 ppm 0 3 (%)	<u>4</u> (%)	<u>(</u>	<u>1</u> %)	400 5 2 (%)	(%)	4
{Urinary sy	stem)																		
kidney	hyaline cast	0 (0)	<5 1 (2)	0	0 (0)	0 (0)	2		0) (0)	(0	1	50> 0 (0)	0 (0)		0 0) (0		(0)
	lymphocytic infiltration	2 (4)	0 (0)	0 (0)	0 (0)	2 (4)	(0)		0	(2 4)	1 (2)	0 (0)	0 (0)		1 2) (0 (0)	0 (0)	0 (0)
	inflammatory polyp	0 (0)	2 (4)	0 (0)	0 (0)	2 (4)	2 (4)) (1	5 0	(0 0)	2 (4)	8 (16)	0 *	(1 2)		3 (6)	0 (0)
	hydronephrosis	(2)	0 (0)	(2)	0 (0)		(2		7 0 * 4) (0)	(0 0)		11 (22)	0 **		4 8)	0 (0)	7 (14)	0 (0)
	papillary necrosis	0 (0)	0 (0)	(0)	0 (0)	0 (0)	(0		0 0	(0)	0 (0)	0 (0)	0 (0)		1 2)	1 (2)	(0	0 (0
	mineralization:papilla	1 (2)	0 (0)	0 (0)	0 (0)	i (2)	(0) (0 0	(0	(0)	(0)	0 (0)	(1 2)	0 (0)	(0	0) (
	mineralization:pelvis	0 (0)	0 (0)	(0)	0 (0)	0 (0)	(0)) (0 0	(2 4)	(0)	0 (0)	0 (0)	(4 8)			: 0) (0
	mineralization:cortex	(2)	0 (0)	0 (0)	0 (0)	(2)			0 0	(0 0)	(0)	0 (0	0 (0)	(0 0)	(0)) (0

^{3 :} Marked 4 : Severe Grade 1 : Slight 2 : Moderate

(HPT150)

BAIS4

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

b b: Number of animals with lesion

c:b/a*100 (c)

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

STUDY NO. : 0372 ANIMAL

: MOUSE Crj:BDF1

REPORT TYPE : A1 : FEMALE

2000 ppm 4000 ppm 1000 ppm Group Name Control 50 50 50 No. of Animals on Study Grade (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) Findings_ Organ_ (Urinary system) <50> <50> <50> <50> kidney 0 0 0 0 0 0 dilatation:tubular lumen (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (2)(0)(0)(0) 0 2 0 glomerulosclerosis (0)(0)(2)(0) (0)(0)(0)(0) (0) (0) (0) (0) (0)(0)(4)(0) 0 6 0 0 desquamation:pelvis (10) (0) (0) (0) (12) (2) (0) (0) (14) (0) (0) (0) (2)(0)(0)(0) 0 0 0 0 urothelial hyperplasia:pelvis (2)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) ⟨50⟩ <50> (49) ⟨50⟩ urin bladd 0 0 0 0 0 0 dilatation (0)(0)(0)(0) (0) (0) (0) (0) (2)(0)(0)(0) (0)(0)(0)(0) (Endocrine system) <50> pituitary 0 0 0 0 0 0 1 0 0 0 0 0 angiectasis

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

Grade

1 : Slight

2 : Moderate

3 : Marked

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

4 : Severe

< a >

a : Number of animals examined at the site

b

(c)

b: Number of animals with lesion

c:b/a * 100 Significant difference ; * : P \leq 0.05 ** : P \leq 0.01 Test of Chi Square

(HPT150)

BAIS4

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

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

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1

SEX : FEMALE PAGE: 27

Organ	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%)
{Endocrine s	ystem)				
pituitary		<50>	<50>	<50≻	<50>
	cyst	5 0 0 0 (10) (0) (0) (0)	5 0 0 0 (10) (0) (0) (0)	8 0 0 0 0 (16) (16) (16) (16)	9 0 0 0
	hyperplasia	5 6 1 0 (10) (12) (2) (0)	8 2 0 0 (16) (4) (0) (0)	3 1 0 0 (6) (2) (0) (0)	4 0 0 0 * (8) (0) (0) (0)
thyroid	inflammatory infiltration	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 0 0 0 0 0 0 0	<pre></pre>	<49> 0 0 0 0 0 0 0 0 0 0 0
	cystic thyroid follicle	2 0 0 0 0 (4) (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	1 0 0 0 0 (2) (0) (0)	1 0 0 0 0 (2) (0) (0)
adrena]	hemorrhage	(49) 0 0 0 0 (0) (0) (0) (0)	(49) 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)
	extramedullary hematopoiesis	0 0 0 0 0 (0) (0)	2 0 0 0 0 (4) (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)
	spindle cell hyperplasia	23 24 0 0 (47) (49) (0) (0)	18 29 0 0 (37) (59) (0) (0)	17 32 1 0 (34) (64) (2) (0)	36 11 0 0 * (72) (22) (0) (0)
Grade <a>> b (c) Significant	1: Slight 2: Moderate a: Number of animals examined at t b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **:	3: Marked 4: Severe Line site P ≤ 0.01 Test of Chi Square			

(UPT150)

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1
SEX : FEMALE

)rgan	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
Endocrine sys	stem)				
drenal	hyperplasia:cortical cell	2 0 0 0 (4) (0) (0) (0)	<49> 0 2 0 0 (0) (4) (0) (0)	<50> 1 1 0 0 (2) (2) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
	focal fatty change:cortex	0 2 0 0 (0) (4) (0) (0)	1 0 0 0 0 (2) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
Reproductive	system)				
ovary	angiectasis	(50) 0 2 0 0 (0) (4) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
	thrombus	0 0 0 0 0 (0) (0)	1 0 3 0 (2) (0) (6) (0)	0 0 1 0 (0) (2) (0)	0 0 0 0 0 (0) (0)
	cyst	8 3 0 0 (16) (6) (0) (0)	5 1 0 0 (10) (2) (0) (0)	4 2 0 0 (8) (4) (0) (0)	3 2 0 0 (6) (4) (0) (0)
uterus	thrombus	<50> 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 1 0 (0) (0) (2) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1

: FEMALE SEX

Organ	No	oup Name Control of Animals on Study 50 ade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
Reproductive	system)				
terus	cystic endometrial hyperplasia	<50> 28 6 0 0 (56) (12) (0) (0)	<50> 22 2 0 0 (44) (4) (0) (0)	24 5 1 0 (48) (10) (2) (0)	32 1 0 0 (64) (2) (0) (0)
	xanthogranuloma	0 0 2 0 (0) (4) (0)	0 0 0 0 0 (0) (0)	0 0 1 0 (0) (2) (0)	0 0 0 0 0 (0) (0)
/agina	epidermal cyst	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	2 0 0 0 (4) (0) (0) (0)	<50> 0 0 0 0 0 0 0 0 0 0 0
ammary gl	galactocele	<50> 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	50> 1 0 0 0 (2) (0) (0) (0
{Nervous syst	Lem)				
braîn	vacuolic change	0 0 0 0 0 (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	(0) (0) (0) (0
	mineralization	3 0 0 0	6 0 0 0 (12) (0) (0) (0)	3 0 0 0 0 (6) (6) (70) (70)	1 0 0 0 0 (2) (0) (0) (0)
Grade < a > b (c)	1: Slight 2: Moderate 3: a: Number of animals examined at the sit b: Number of animals with lesion c: b / a * 100	Marked 4: Severe e	,	·	

ALL ANIMALS (0-105W)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE

rgan	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%) (%)	1000 ppm 50 1 2 3 4 (%) (%) (%) (%)	2000 ppm 50 1 2 3 4 (%) (%) (%) (%)	4000 ppm 50 1 2 3 4 (%) (%) (%) (%)
lervous sys	tem)				
rain	perivascular inflammation	<50> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	(50) 1 0 0 0 (2) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)
pinal cord	opidormal cyst	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)	(50) (0)(0)(0)(0)(0)
Special sem	ise organs/appendage)				
ye	degeneration:cornea	3 0 0 0 (6) (0) (0) (0)	(50) 4 0 0 0 (8) (0) (0) (0)	<pre></pre>	(50) 0 0 0 0 (0) (0) (0) (0)
arder gl	degeneration	(0) (0) (0) (0)	(50) 0 1 0 0 (0) (2) (0) (0)	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
	lıyperplasia	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 1 1 0 (0) (2) (2) (0)	2 1 0 0 (4) (2) (0) (0)
(Musculoske	letal system)				
uscle	mineralization	(50> 1 0 0 0 (2) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	<50> 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

ALL ANIMALS (0-105W)

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1

SEX : FEMALE

4000 ppm Control 1000 ppm 2000 ppm Group Name 50 50 50 No. of Animals on Study 50 Grade 3 (%) (%) (%) (%) (%) (%) Findings. (%) (%) (%) (%) (%) {Body cavities} <50> <50> pleura 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 thrombus (0) (0) (0) (0) (0)(0)(0)(0) (2)(0)(0)(0) (0)(0)(0)(0) <50> <50> <50> peritoneum <50> 0 0 0 0 0 0 0 0 1 0 0 0 0 0 0 0 thrombus (0)(0)(0)(0) (0) (0) (0) (0) (2)(0)(0)(0) (0)(0)(0)(0) <50> thoracic ca <50> <50> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 1 0 hemorrhage (0)(2)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) 1 : Slight 2 : Moderate 3 : Marked 4 : Severe Grade < a > a : Number of animals examined at the site b: Number of animals with lesion b (c) c:b/a*100 Significant difference ; * : $P \le 0.05$ ** : $P \le 0.01$ Test of Chi Square

(HPT150)

BATS4

APPENDIX L 3

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOUSE: MALE: SACRIFICED ANIMALS

(2-YEAR STUDY)

SACRIFICED ANIMALS (105W)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

rgan	Group Name No. of And Grade	Control mals on Study 38 1 2 3 4 (%) (%) (%) (%)	500 ppm 38 1 2 3 4 (%) (%) (%) (%)	1000 ppm 42 1 2 3 4 (%) (%) (%) (%)	2000 ppm 39 1 2 3 4 (%) (%) (%) (%)
Integumentar	y system/appandage)				
kin/app	ulcer	(0) (0) (0) (0) (0) (0) (0) (0)	38> 0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	(39) 0 2 0 0 (0) (5) (0) (0)
(Respiratory	system}				
nasal cavit	eosinophilic change:olfactory epithelium	<38> 17 0 0 0 (45) (0) (0) (0)	<38> 10 0 0 0 (26) (0) (0) (0)	\(\langle 42 \rangle \) 19	39> 17 0 0 0 (44) (0) (0) (0)
	eosinophilic change:respiratory epithelium	25 0 0 0 (66) (0) (0) (0)	21 0 0 0 (55) (0) (0) (0)	22 2 0 0 (52) (5) (0) (0)	27 6 2 0 * (69) (15) (5) (0)
	respiratory metaplasia:olfactory epithelium	12 0 0 0 (32) (0) (0) (0)	7 0 0 0 (18) (0) (0) (0)	10 0 0 0 (24) (0) (0) (0)	8 0 0 0 (21) (0) (0) (0)
	respiratory metaplasia:gland	22 2 0 0 (58) (5) (0) (0)	19 2 0 0 (50) (5) (0) (0)	19 2 0 0 (45) (5) (0) (0)	26 0 0 0 (67) (0) (0) (0)
	inflammation:transitional epithelium	0 0 0 0 0 (0) (0)	1 0 0 0 0 (3) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0
nasopharynx	eosinophilic change	· <38> 1 0 0 0 (3) (0) (0) (0)	<38> 0 0 0 0 (0) (0) (0) (0)	<42> 1 0 0 0 (2) (0) (0) (0)	<39> 2 0 0 0 (5) (0) (0) (0)

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

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

b : Number of animals with lesion ь

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

(HPT150)

BAIS4

SACRIFICED ANIMALS (105W)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1

SEX : MALE

rgan	N	coup Name	500 ppm 38 1 2 3 4 (%) (%) (%) (%)	1000 ppm 42 1 2 3 4 (%) (%) (%) (%)	2000 ppm 39 1 2 3 4 (%) (%) (%) (%)
Respiratory s	system)				
crachea	eosinophilic change	<38> 0 0 0 0 (0) (0) (0) (0)	<38> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	<pre></pre>
ung	hemorrhage	(0) (0) (0) (0) (0)	(0) (0) (0) (0) (0) (0) (0) (0)	42> 1 0 0 0 (2) (0) (0) (0)	<39> 0 0 0 0 0 0 0 0 0 0 0
	inflammatory infiltration	1 0 0 0 (3) (0) (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (2) (0) (0)	0 0 0 0 0 (0) (0)
	granulation	0 0 0 0 0 (0) (0)	0 0 0 0 0	0 0 1 0	0 0 0 0 0 (0) (0) (0)
	accumulation of foamy cells	1 1 0 0 (3) (3) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	bronchiolar-alveolar cell hyperplasia	12 0 0 0 (32) (0) (0) (0)	15 0 0 0 (39) (0) (0) (0)	15 0 0 0 (36) (0) (0) (0)	14 0 0 0 (36) (0) (0) (0
{ lematopoieti	c system)				
bone marrow	thrombus	<pre></pre>	<38> 0 0 0 0 0 0 0 0 0 0 0	<42> 0 0 0 0 (0) (0) (0) (0)	(39) 1 0 0 0 (3) (0) (0) (0)
Grade (a)	1: Slight 2: Moderate 3 a: Number of animals examined at the si b: Number of animals with lesion c: b / a * 100	: Marked 4 : Severe te			

STUDY NO. : 0372 HISTOPATHOLOGICAL I ANIMAL : MOUSE Crj:BDF1 SACRIFICED ANIMALS

REPORT TYPE : A1

SEX : MALE

rgan	Findings		ontrol 38 3 4 (%) (%)	500 ppm 38 1 2 3 4 (%) (%) (%) (%)	1000 ppm 42 1 2 3 4 (%) (%) (%) (%)	2000 ppm 39 1 2 3 4 (%) (%) (%) (%)
llematopoieti	c system)	·				
one marrow	decreased hematopoiesis	0 0	38> 0 0 (0) (0)	0 0 0 0 (0) (0) (0) (0)	1 0 0 0 (2) (0) (0)	<pre></pre>
	myelofibrosis	1 0 (3) (0)	0 0 (0)	1 0 0 0 0 (3) (0) (0)	1 0 0 0 (2) (0) (0) (0)	1 0 0 0 0 (3) (0) (0) (0)
	erythropolesis:increased	1 0 (3) (0)	0 0	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0)	1 0 0 0 0 (3) (0) (0)
	megakaryocyte:increased	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)
spleen	deposit of hemosiderin	0 0	(38) 0 0 0 (0) (0)	38> 1 0 0 0 (3) (0) (0) (0)	<42> 0 0 0 0 0 0 0 0 0 0 0 0	39> 2 0 0 0 (5) (0) (0) (0)
	deposit of melanin	2 0 (5) (0)	0 0	0 0 0 0 0 (0) (0)	2 0 0 0 0 (5) (0) (0)	0 0 0 0 0
	extramedullary hematopoiesis	3 1 (8) (3)	2 0	5 2 2 0 (13) (5) (5) (0)	10 3 2 0 (24) (7) (5) (0)	11 2 1 0 (28) (5) (3) (0)
	hyperplasia:mast cell	0 0	0 0	0 0 0 0 0 (0) (0)	i 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 ; * : $P \le 0.05$ ** : $P \le 0.01$ Test of Chi Square

SACRIFICED ANIMALS (105W)

 \searrow

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

STUDY NO. : 0372

)rgan	Group No. o Grade Findings	f Animals on Study 38	500 ppm 38 1 2 3 4 (%) (%) (%) (%)	1000 ppm 42 1 2 3 4 (%) (%) (%) (%)	2000 ppm 39 1 2 3 4 (%) (%) (%) (%)
{ lematopoietic	c system)				
spleen	follicular hyperplasia	385> 1 0 0 0 (3) (0) (0) (0)	<pre></pre>	2 1 0 0 (5) (2) (0) (0)	<pre></pre>
{Circulatory :	system)				
neart	granulation	<38> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	(42>) i 0 0 0 (2) (0) (0) (0)	(39) 0 0 0 0 (0) (0) (0) (0)
Digestive sy	stem)				
ooth	dysplasia	<38> 0 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	<42> 0 0 0 0 0 0 0 0 0 0 0 0	(0) (0) (0) (0) 0 0 0 0 0 0 0 0
iongue	arteritis	38> 0 0 0 0 (0) (0) (0) (0)	(0) (0) (0) (0) (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	39> 1 0 0 0 (3) (0) (0) (0)
salivary gl	atrophy	38> 0 0 0 0 0 0 0 0	<38> 0 0 0 0 0 0 0 0 0	<42> 0 0 0 0 (0) (0) (0) (0)	39> 1 0 0 0 (3) (0) (0) (0)
Grade < a > b (c)	1: Slight 2: Moderate 3: Ma a: Number of animals examined at the site b: Number of animals with losion c: b/a * 100	rked 4: Severe			

(HPT150)

BALS4

SACRIFICED ANIMALS (105W)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

SEX : MALE

rgan	Findings	Group Name No. of Animals on Study Grade	Cont 38 2 (%)	3 (%)	<u>4</u> (%)	1 (%)		38 38 (9	3 4		<u>1</u> (%)		1000 42 2 (%)	3 (%)	<u>4</u> (%)		<u>1</u> (%)		2000 39 2 %)	3 (%)	 <u>4</u> %)
Digestive sy	stem)																				
alivary gl	inflammatory infiltration	0 (0)	<38) 0 (0) (0	(0) -	(3)	0		0 0 0) (0		0 (0)		<42 0 0)	0	0 (0)		0 (0)		<39 0 0) (0 (0)	0 0)
	fibrosis:focal	0 (0)	0 (0) (0	0 (0)	0 (0)	0		0 0 0) (0		0 (0)		0 0)	0 (0)	(0)		0 (0)		1 3) (0 (0)	0 0)
stomach	mineralization	3 (8)	<38 0 (0) (0	0 (0)	0 (0)	0		0 0 0) (0		0		<42 0 0)	0	0 (0)	,	0 (0		(39 0 (39	9> 0 (0)	0 0)
	inflammatory infiltration	5 (13)	0 (0) (0	0 (0)	0 (0)	(0		0 0		0		0	0 (0)	0 (0)	*			0	0 (0)	0 0)
	hyperplasia:forestomach	0 (0)	0 (0) (0 (0)	0 (0)	0 (0)	((0 (1 (2		0	0 (0)	0 (0)		(3		0 0)	0 (0)	0 0)
	erosion:glandular stomach	2 (5)	0 (0) (0 (0)	0 (0)	0 (0)	(())) (0 ((5	; i) (0	0 (0)	0		(0		0	0 (0)	0
	ulcer:glandular stomach	0 (0)	0 (0) (0 (0)	0 (0)	1 (3)	((0 (o o)	((0 0)	0 (0)	0))) (0 0)	(0)	0 0)
	hyperplasia:glandular stomach	5 (13)	0 (0)	1 (3)	0 (0)	1 (3)) ()	0 (0 0)	((0 0)	0 (0)	0 (0	*	(3		0)	(0)	0 0)

^{3 :} Marked Grade 1 : Slight 2 : Moderate 1 : Severe < a >

a : Number of animals examined at the site

b: Number of animals with lesion b

⁽c) c:b/a*100

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

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) SACRIFICED ANIMALS (105W)

gan	Findings.	Group Name Control No. of Animals on Study 38 Grade 1 2 3 4 (%) (%) (%) (%) (%)	500 ppm 38 1 2 3 4 (%) (%) (%) (%)	1000 ppm 42 1 2 3 4 (%) (%) (%) (%)	2000 ppm 39 1 2 3 4 (%) (%) (%) (%)
igestive :	system)				
omach	ectopia:glandular stomach	2 0 0 0 (5) (0) (0) (0)	38> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	39> 0 0 0 0 (0) (0) (0) (0)
er	angiectasis	38> 1 0 0 0 (3) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	(42> 0 0 0 0 (0) (0) (0) (0)	<39> 0 0 0 0 0 0 0 0 0 0 0
	necrosis:central	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0)	0 0 0 0 0 (0) (0)
	necrosis:focal	0 1 0 0 (0) (0) (0)	2 0 0 0 0 (5) (0) (0)	2 0 0 0 0 (5) (0) (0)	3 0 0 0 0 (8) (0) (0) (0)
	necrosis:single cell	3 0 0 0 0 (8) (0) (0) (0)	1 0 0 0 (3) (0) (0)	1 0 0 0 0 (2) (0) (0)	0 0 0 0 0 (0) (0)
	fatty change	1 0 0 0 (3) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)
	degeneration:focal	0 0 0 0 0 (0)	1 0 0 0 0 (3) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0
	inflammatory infiltration	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0
ade a > b	1: Slight 2: Moderate a: Number of animals examined at the b: Number of animals with lesion c: b/a*100	3 : Marked 4 : Severe site			

(HPT150)

BAIS4

STUDY NO. : 0372 REPORT TYPE : A1 SEX : MALE

ANIMAL : MOUSE Crj:BDF1

gan	Findings	Group Name	2 (%)	strol 3 3 (%)	<u>4</u> (%)	<u>1</u> (%)		00 ppm 38 3 (%)	4_	<u>(</u>	<u>(</u> %)	1000 42 2 (%)	3 (%)	<u>4</u> (%)	1(%		2000 39 2 (%)		4 (%)
igestive	system)																		
ver	lymphocytic infiltration	0 (0)	<3 0 (0)	0	0 (0)	1 (3)	0		0 (0)		0 0) (<4: 0 0)	2> 0 (0)	0 (0)	1 (3		<39 0 0) (0 (0)	0 (0)
	granulation	30 (79)	0 (0)	0 (0)	0 (0)	29 (76)	0 (0)	0 (0)	0 (0)	2 (6	7 4) (2 5)	0 (0)	0 (0)	24 (62		0	0	0 (0)
	extramedullary hematopoiesis	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)		0 (0)		1 2) (0 0)	0 (0)	0 (0)) ()	0 (0)	0 (0)	0 (0)
	clear cell focus	3	0 (0)	0 (0)	0 (0)	6 (16)	0 (0)	0 (0)	0 (0)	(1 2) (1 2)	0 (0)	0 (0)	((0 0) (0	0 (0)	0
	acidophilic cell focus	1 (3)	1 (3)	0 (0)	0 (0)	9 (24)	1 (3)	0 (0)	0) (0) (5 2) (4 10)	0 (0)	0 (0)		3 8) (0	0 (0)	0)
	basophilic cell focus	2 (5)	0 (0)	0 (0)	0 (0)	4 (11)	0 (0)	0	0 (0)	(:	6 (4) (3 7)	0 (0)	0 (0)		7 8) (1 3)	1 (3)	((
	mixed cell focus	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)	((
	bile ductular proliferation	0 (0)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)) (0)	(0	0	0 (0)	0 (0)		0 0) (0	0 (0)	

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

b b : Number of animals with lesion

⁽c) c:b/a * 100

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

PAGE: 8

BAIS4

STUDY NO. : 0372

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

gan	Group Name No. of Anim Grade	Control als on Study 38 1 2 3 4 (%) (%) (%) (%)	500 ppm 38 1 2 3 4 (%) (%) (%) (%)	1000 ppm 42 1 2 3 4 (%) (%) (%) (%)	2000 ppmi 39 1 2 3 4 (%) (%) (%) (%)
)igestive sys	tem)				
ver	biliary cyst	3 0 0 0 (8) (0) (0) (0)	385 3 0 0 0 (8) (0) (0) (0)	3 0 0 0 (7) (0) (0) (0)	(39) 1 0 0 0 (3) (0) (0) (0)
	focal fatty change	2 0 0 0 0 (5) (0) (0)	1 0 0 0 0 (3) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
ali bladd	cyst	<35> 0 0 0 0 0 0 0 0 0 0 0	38> 1 0 0 0 (3) (0) (0) (0)	41> 1 0 0 0 (2) (0) (0) (0)	(36) 0 0 0 0 (0) (0) (0) (0)
	eosinophilic change	3 0 0 0 0	2 0 0 0 0 (5) (0) (0)	3 1 0 0 (7) (2) (0) (0)	0 1 0 0 (0)
	hyperplasia	0 0 0 0 0 (0) (0) (0)	12 0 0 0 ** (32) (0) (0) (0)	8 0 0 0 * (20) (0) (0)	8 0 0 0 ***
oancreas	atrophy	<38> 0 1 0 0 (0) (3) (0) (0)	(38) 0 0 0 0 (0) (0) (0) (0)	<42> 0 0 0 0 0 0 0 0 0 0 0 0	<pre></pre>
{Urinary sys	tem)				(0.)
kidney	infarct	<pre></pre>	1 0 0 0 (3) (0) (0) (0)	442> 1 0 0 0 (2) (0) (0) (0)	(39) 0 0 0 0 (0) (0) (0) (0)
Grade < a > b (c)	1: Slight 2: Moderate 3: Marked a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; *: P \le 0.05 **: P \le 0.01	4 : Severe Test of Chi Square			

STUDY NO. : 0372 : MOUSE Crj:BDF1

REPORT TYPE : A1 : MALE SEX

ANIMAL

1000 ppm 2000 ppm Control 500 ppm Group Name 39 38 42 No. of Animals on Study 38 3 Grade (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) Findings Organ_ (Urinary system) ⟨42⟩ <39> <38> <38> kidney 0 0 0 0 0 1 0 1 0 cyst (0)(0)(0)(0) (0)(3)(0)(0) (2)(0)(0)(0) (3)(3)(0)(0) 0 0 0 0 0 hyaline droplet 1 0 0 0 (2)(0)(0)(0) (3)(0)(0)(0) (3)(0)(0)(0) (0)(0)(0)(0) 0 0 0 0 0 35 0 0 0 basophilic change (93) (0) (0) (0) (87) (0) (0) (0) (92) (0) (0) (0) (79) (0) (0) (0) 4 1 0 0 0 0 0 0 3 0 0 3 0 lymphocytic infiltration (10) (3) (0) (0) (19) (0) (0) (0) (8)(0)(0)(0) (8)(0)(0)(0) 0 1 0 1 0 0 1 0 0 0 inflammatory polyp (0)(0)(5)(0) (0)(0)(3)(0) (0)(2)(0)(0) (0)(3)(0)(0) 0 0 1 0 0 0 0 1 0 hydronephrosis (0)(0)(3)(0) (0)(0)(2)(0) (0)(0)(3)(0) (0)(3)(0)(0) 0 0 0 0 0 0 1 0 0 0 mineralization:pelvis (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (3)(0)(0)(0) 9 0 0 0 11 0 16 0 0 mineralization:cortex (38) (0) (0) (0) (23) (0) (0) (0) (29) (0) (0) (0) (32) (0) (0) (0)

(HPT150)

BAIS4

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

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

b b: Number of animals with lesion

⁽c) c:b/a*100

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

SACRIFICED ANIMALS (105W)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE

rgan		p Name	500 ppm 38 1 2 3 4 (%) (%) (%) (%)	1000 ppm 42 1 2 3 4 (%) (%) (%) (%)	2000 ppm 39 1 2 3 4 (%) (%) (%) (%)
Urinary syst	em)				
rin bladd	dilatation	<pre></pre>	38> 0 0 0 0 (0) (0) (0) (0)	<42> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>
	inflammation	1 0 0 0 0 (3) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0)
{Endocrine s	ystem)				
oituitary	cyst	<36> 2 0 0 0 (6) (0) (0) (0)	<38> 1 0 0 0 (3) (0) (0) (0)	\(\lambda \) \((39) 1 0 0 0 (3) (0) (0) (0)
	hyperplasia	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0)	3 0 0 0 0
	Rathke pouch	0 0 0 0 0 (0) (0)	3 0 0 0 0	3 0 0 0 0 (7) (0) (0) (0)	1 0 0 0 0
thyroid	lymphocytic infiltration	<pre></pre>	<pre></pre>	<pre></pre>	<39> 0 0 0 0 0 0 0 0 0 0 0
Grade <a> b (c)	1: Slight 2: Moderate 3: a: Number of animals examined at the site b: Number of animals with lesion c: b/a*100	Marked 4: Severe			

(HPT150)

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BAIS4

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 : MALE

rgatı	Findings	Group Name Control No. of Animals on Study 38 Grade 1 2 3 4 (%) (%) (%) (%) (%)	500 ppm 38 1 2 3 4 (%) (%) (%) (%)	1000 ppm 42 1 2 3 4 (%) (%) (%) (%)	2000 ppm 39 1 2 3 4 (%) (%) (%) (%)
Endocrine s	ystem)				
hyroid	ultimibranchial body remanet	<38> 0 0 0 0 (0) (0) (0) (0)	385 1 0 0 0 (3) (0) (0) (0)	<pre></pre>	(0) (0) (0) (0) (0) (0) (0) (0)
	C-cell hyperplasia	3 0 0 0 (8) (0) (0) (0)	3 0 0 0 0 (8) (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (3) (0) (0)
	cystic thyroid follicle	0 0 0 0 0	0 0 0 0 0	1 0 0 0 0 (2) (0) (0)	1 0 0 0 0 (3) (0) (0)
adrenal	cyst	<38> 0 0 0 0 0 0 0 0 0 0 0	(38) 0 0 0 0 (0) (0) (0) (0)	\(\langle 42 \rangle \) \(1 0 0 \\ (2) (0) (0) (0) \)	(0) (0) (0) (0)
	spindle-cell hyperplasia	17 0 0 0 (45) (0) (0) (0)	18 2 0 0 (47) (5) (0) (0)	14 1 0 0 (33) (2) (0) (0)	11 0 0 0 (28) (0) (0) (0)
	hyperplasia:cortical cell	6 1 0 0 (16) (3) (0) (0)	11 4 0 0 (29) (11) (0) (0)	8 0 0 0 (19) (0) (0) (0)	5 1 0 0 (13) (3) (0) (0)
{Reproducti	ve system)				
testis	atrophy	<pre></pre>	<38> 2 0 0 0 (5) (0) (0) (0)	<pre></pre>	39> 10 0 0 0 (26) (0) (0) (0)

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE

1000 ppm 2000 ррт 500 ppm Group Name Control 39 38 42 No. of Animals on Study 38 Grade (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) Findings. Organ_ {Reproductive system} <42> <38> ₹38> testis 0 0 0 0 0 0 0 0 35 1 0 0 mineralization (97) (0) (0) (0) (98) (0) (0) (0) (95) (0) (0) (0) (92) (3) (0) (0) 0 0 1 0 0 0 interstitial cell hyperplasia (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (3)(0)(0)(0) 0 0 1 0 0 0 spermatogenic granuloma (0) (0) (0) (0) (0)(0)(0)(0) (0)(0)(0)(0) (3)(0)(0)(0) **〈42〉** <39> <38> <38> epididymis 0 0 0 0 0 0 0 0 0 0 0 0 inflammation (5)(0)(0)(0) (0)(0)(0)(0) (3)(0)(0)(0) (0)(0)(0)(0) spermatogenic granuloma (8)(5)(0)(0) (7)(0)(0)(0) (8)(0)(0)(0) (11) (0) (0) (0) 0 0 0 0 xanthogranuloma (0)(0)(0)(0) (0)(0)(0)(0) (2)(0)(0)(0) (0)(0)(3)(0) <42> <38> <38> prep/cli gl 0 0 0 * 5 0 0 0 7 0 0 0 0 0 0 duct ectasia (13) (0) (0) (0) (5)(0)(0)(0) (18) (0) (0) (0) (24) (0) (0) (0)

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

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

b b: Number of animals with lesion

(c) c:b/a*100

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

(IIPT150)

BAIS4

SEX : MALE

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1

Organ	Grou	o Name Control of Animals on Study 38 = 1 2 3 4 (%) (%) (%) (%)	500 ppm 38 1 2 3 4 (%) (%) (%)	1000 ppm 42 1 2 3 4 (%) (%) (%) (%)	2000 ppm 39 1 2 3 4 (%) (%) (%) (%)
{Nervous sys	tem)				
brain	mineralization	<pre></pre>	38> 8 0 0 0 * (21) (0) (0) (0)	\(\langle 42 \rangle \) 17	39> 12 0 0 0 (31) (0) (0) (0)
	gliosis	2 0 0 0 0 (5) (0) (0)	0 0 0 0	0 0 0 0 0 0 (0)	3 0 0 0
{Special sen	nse organs/appendage)				
eye	degeneration:cornea	<38> 0 0 0 0 0 0 0 0 0 0 0	<pre></pre>	<pre></pre>	<pre></pre>
llarder gl	hyperplasia	37> 1 0 0 0 (3) (0) (0) (0)	(38) 0 1 0 0 (0) (3) (0) (0)	<42> 0 0 0 0 0 0 0 0 0	<pre></pre>
{Body caviti	ies)				
peritoneum	xanthogranuloma	(0) (0) (0) (0)	(0) (0) (0) (0)	(42> 0 0 1 0 (0) (0) (2) (0)	39> 0 0 0 0 (0) (0) (0) (0)
Grade < a > b (c) Significant	1: Slight 2: Moderate 3: M a: Number of animals examined at the site b: Number of animals with lesion c: $b / a * 100$ difference; $*: P \le 0.05$ **: $P \le 0$.				

(IIPT150)

BAIS4

APPENDIX L 4

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOUSE: FEMALE: SACRIFICED ANIMALS

(2-YEAR STUDY)

SACRIFICED ANIMALS (105W)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE

1000 ppm 2000 ppm 4000 ppm Group Name Control No. of Animals on Study 24 29 28 34 2 3 Grade (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) Organ_ Findings_ {Integumentary system/appandage} <28> <34> <29> skin/app <24> 0 0 0 0 0 0 0 0 0 0 inflammation (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (4)(0)(0)(0) 0 0 0 0 scar:dermis (0)(0)(0)(0) (0)(0)(0)(0) (0)(4)(0)(0) (0)(0)(0)(0) {Respiratory system} nasal cavit <24> 0 0 0 0 exudate (4)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) 0 0 angiectasis (12) (0) (0) (0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) eosinophilic change:olfactory epithelium 5 0 0 0 0 (21) (0) (0) (0) (0)(0)(0)(0) (29) (0) (0) (0) (41) (0) (0) (0) eosinophilic change:respiratory epithelium 16 3 2 0 17 10 0 0 6 21 1 0 ** 5 19 10 0 ** (67) (13) (8) (0) (59) (34) (0) (0) (21) (75) (4) (0) (15) (56) (29) (0) respiratory metaplasia:olfactory epithelium 2 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)

(HPT150)

BATS4

Grade

^{1 :} Slight

^{2 :} Moderate

^{3 :} Marked

^{4 :} Severe

⁽a)

a: Number of animals examined at the site

b b: Number of animals with lesion

⁽c) c:b/a * 100

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

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

REPORT TYPE : A1 : FEMALE SEX

(IIPT150)

SACRIFICED ANIMALS (105W)

PAGE: 15

BA1S4

Organ	1	Froup Name Control to of Animals on Study 24 Grade 1 2 3 (%) (%) (%)	4 <u>1</u> (%)	1000 ppm 29 2 3 4 0 (%) (%) (%)	2000 ppm 28 1 2 3 4 (%) (%) (%) (%)	4000 ppm 34 1 2 3 4 (%) (%) (%) (%)
{Respiratory s	system]					
nasal cavit	respiratory metaplasia:gland	24> 10 0 0 (42) (0) (0)	0 13 (0) (45)	<29> 0 0 0) (0) (0) (0)	28> 12 5 0 0 (43) (18) (0) (0)	23 3 0 0 * (66) (9) (0) (0)
nasopliarynx	eosinophilic change	(24) 1 1 0 (4) (4) (0)	0 2 (0) (7	<29> 0 0 0 0 0 0 0 0 0 0 0	288> 2 0 0 0 (7) (0) (0) (0)	9 0 0 0 * (26) (0) (0) (0)
lung	inflammatory infiltration	2 0 0 (8) (0) (0)	0 0	<29> 0 0 0 0 0 0 0 0	28> 1 0 0 0 (4) (0) (0) (0)	34> 0 0 0 0 (0) (0) (0) (0)
	accumulation of foamy cells	1 0 0 (4) (0) (0)	0 0	0 0 0 0	0 0 1 0 (0) (4) (0)	0 0 0 0 0 (0) (0)
	bronchiolar-alveolar cell hyperplasia	5 0 0 (21)(0)(0)	0 10	0 0 0 0	7 0 0 0 (25) (0) (0) (0)	12 0 0 0 (35) (0) (0) (0)
{Hematopoieti	c system)					
bone marrow	myelofibrosis	3 0 0 (13) (0) (0)		<29> 3	28> 1 1 0 0 (4) (4) (0) (0)	34> 2 0 0 0 (6) (0) (0) (0)
Grade <a>> b (c) Significant d	a : Number of animals examined at the s. b : Number of animals with lesion c : b / a * 100					

SACRIFICED ANIMALS (105W)

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE

gail	Findings	Group Name Control No. of Animals on Study 24 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 29 1 2 3 4 (%) (%) (%)	2000 ppth 28 1 2 3 4 (%) (%) (%) (%)	4000 ppm 34 1 2 3 4 (%) (%) (%) (%)
lematopoietic	c system)				
one marrow	megakaryocyte:increased	<24> 0 0 0 0 0 0 0 0 0 0 0	<pre></pre>	(28) 0 0 0 0 (0) (0) (0) (0)	34> 1 0 0 0 (3) (0) (0) (0)
	granulopoiesis:increased	0 1 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0)
spleen	atrophy	<24> 0 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	<pre></pre>	(34) 1 0 0 0 (3) (0) (0) (0)
	angiectasis	0 0 0 0 0 (0) (0)	1 0 0 0 0 (3) (0) (0) (0)	0 0 0 0 0 0 (0)	0 0 0 0 0
	deposit of hemosiderin	1 0 0 0 (4) (0) (0) (0)	8 0 0 0 (28) (0) (0) (0)	1 0 0 0 0 (4) (0) (0)	2 0 0 0 0 (6) (0) (0)
	deposit of melanin	2 0 0 0 (8) (0) (0) (0)	0 0 0 0 0 0 (0)	1 0 0 0 0 (4) (0) (0)	4 0 0 0 0 (12) (0) (0) (0)
	extramodullary hematopoiesis	11 2 0 0 (46) (8) (0) (0)	5 1 0 0 * (17) (3) (0) (0)	8 3 1 0 (29) (11) (4) (0)	7 1 1 0 (21) (3) (3) (0)
	follicular hyperplasia	0 0 0 0 0 (0) (0)	4 0 0 0 0 (14) (0) (0) (0)	1 1 0 0 (4) (4) (0) (0)	1 1 0 0 0 (3) (3) (0) (0)

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

BAIS4

PAGE: 16

(HPT150)

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

b b: Number of animals with less (c) c: b/a * 100

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

SACRIFICED ANIMALS (105W)

ANIMAL : MOUSE Cr j: BDF1

REPORT TYPE : A1 SEX : FEMALE

STUDY NO. : 0372

4000 ppm 2000 ppm 1000 ppm Control Group Name 34 28 29 24 No. of Animals on Study Grade (%) (%) (%) (%) (%) (%) (%) Findings_ Organ_ (Digestive system) <29> <24> tooth 0 0 0 0 1 0 0 0 0 0 0 0 inflammation (0) (4) (0) (0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) <29> <24> stomach 0 0 0 0 0 0 1 1 0 0 0 0 inflammatory infiltration (0)(0)(0)(0) (4)(4)(0)(0) (3)(0)(0)(0) (0)(0)(0)(0) 0 0 0 0 0 0 0 0 0 0 0 ulcer:forestomach (0)(0)(0)(0) (0)(0)(0)(0) (0)(3)(0)(0) (0)(0)(0)(0) 0 0 0 0 0 0 0 0 1 1 0 0 0 hyperplasia: forestomach (0)(0)(0)(0) (0)(4)(0)(0) (0)(0)(0)(0) (4)(0)(0)(0) 0 0 1 0 0 0 0 0 0 0 0 0 0 0 erosion:glandular stomach (0)(0)(0)(0) (0)(0)(0)(0) (3)(0)(0)(0) (0)(0)(0)(0) 0 0 0 0 0 1 0 0 0 ulcer:glandular stomach (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (4)(0)(0)(0) <34> ₹28> <24> <29> small intes 0 0 0 0 0 0 0 0 0 0 1 0 0 ulcer (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 ; * : $P \le 0.05$ ** : $P \le 0.01$ Test of Chi Square

STUDY NO. : 0372

ANIMAL

: MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE

4000 ррт 1000 ppm 2000 ppm Group Name Control 28 34 No. of Animals on Study 24 29 3 Grade (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) Organ_ Findings_ (Digestive system) <29> <34> <24> liver 0 0 0 0 0 0 0 0 2 0 0 angiectasis (4)(8)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) 0 0 0 1 0 0 0 1 0 0 necrosis: focal (0)(0)(0)(0) (3)(0)(0)(0) (4)(0)(0)(0) (3)(0)(0)(0) 0 0 0 0 0 0 0 0 0 necrosis:single cell 1 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 degeneration: focal (0)(0)(0)(0) (0)(0)(0)(0) (4)(0)(0)(0) (0)(0)(0)(0) 0 0 0 0 0 0 0 1 0 0 atrophy:focal (0)(0)(0)(0) (0)(3)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) 0 0 0 0 0 0 0 1 0 0 0 1 0 0 0 inflammatory infiltration (3)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (4)(0)(0)(0) 0 0 0 0 0 0 lymphocytic infiltration 1 0 0 0 (0)(0)(0)(0) (0)(0)(0)(0) (7)(0)(0)(0) (4)(0)(0)(0) 8 0 0 0 8 0 3 0 0 11 0 0 0 granulation (32) (0) (0) (0) (33) (0) (0) (0) (28) (0) (0) (0) (11) (0) (0) (0)

Test of Chi Square

Grade

^{1 :} Slight

^{2 :} Moderate

^{3 :} Murked

^{4 :} Severe

⁽a)

a: Number of animals examined at the site

b

b : Number of animals with lesion

⁽c) c:b/a*100

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

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

 \smile

REPORT TYPE : A1 : FEMALE SEX

Prgan	Findings	Group Name No. of Animals on Study Grade (%)	Cont 24 2 (%)	3 (%)	<u>4</u> (%)	<u>1</u> (%)	1000 25 2 (%)	3 (%)	<u>4</u> (%)	1(%)		2000 28 2 (%)		(%)	<u>1</u> (%)	4000 34 2 (%)	0 ррт 4 <u>3</u> (%)	 <u>4</u> (%)
Digestive	system)																		
iver	inflammatory cell nest	17 (71) (<24> 0 0) (0	0 (0)	16 (55) (<2 0 0)	0	0 (0)	18 (64)		<28 0 0) (0	0 (0)	9 (26		<3 0 0)	(0)	0 *== 0)
	extramedullary hematopoiesis	3 (13) (0 (0 0)	0 (0)	6 (21)	0 (0)	0 (0)	0 (0)	5 (18)		0 (0	0 (0)	0 (0)	0 (0 0)	0 (0)	0 0)
	clear cell focus	(0) (0 (0) (0 0)	0 (0)	4 (14)	0 (0)	0 (0)	0 (0)	2 (7)	(0 0) 1	0 (0)	0 (0)	(18		0 0)	2 (6)	0 * 0)
	acidophilic cell focus	1 (4) (0 (0) (0	1 (4)	3 (10)	1 (3)	0 (0)	0 (0)	3 (11)	(0	0 (0)	0 (0)	(29		3 9)	(3)	0 * 0)
	basophilic cell focus	0 (0) (0 (0) (0 (0)	0 (0)	5 (17)	1 (3)	0 (0)	0 (0)	4 (14)	(0 0)	(0)	0 (0)		7 1) (1 3)	0 (0)	0 * 0)
	bile ductular proliferation	(8)	0 (0) (0 (0)	0 (0)	4 (14)	0 (0)	(0)	0 (0)	7 (25)) (0	0 (0)	(0)		4 2) (0 0)	(0	0
	biliary cyst	2 (8)	1 (4) (0 (0)	0 (0)	7 (24)	0 (0)		0 (0)	3 (11)) (0)	0 (0)	0 (0)		2 6) (0 (0)	(0	0
	focal fatty change	0 (0)	0 (0) (0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	(0)		0 0)	0 (0)	0 (0)		0 0) (0 (0)	0 (0	0 0)

Grade

1 : Slight

2 : Moderate

3 : Marked

4 : Severe

< a >

a: Number of animals examined at the site

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

(c)

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

ANIMAL : MOUSE Crj:BDF1

STUDY NO. : 0372 REPORT TYPE : A1

: FEMALE

rgan	Findings	Group Name Control No. of Animals on Study 24 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 29 1 2 3 4 (%) (%) (%) (%)	2000 ppm 28 1 2 3 4 (%) (%) (%)	4000 ppm 34 1 2 3 4 (%) (%) (%) (%)
Digestive sy	vstem)				
all bladd	dilatation	(235) 0 0 0 0 (0)(0)(0)(0)(0)	<pre></pre>	0 0 0 0 (0) (0) (0) (0)	32> 0 0 0 0 (0) (0) (0) (0)
	eosinophilic change	2 0 0 0 (9) (0) (0) (0)	2 2 0 0 (7) (7) (0) (0)	3 0 0 0 (11) (0) (0) (0)	0 1 0 0 (0) (0)
	hyperplasia	0 0 0 0 0 (0)	1 0 0 0 0 (3) (0) (0) (0)	12 0 0 0 *** (43) (0) (0) (0)	9 0 0 0 0 0 (28) (0) (0) (0)
(Urinary sys	rtem}				
idney	infarct	<24> 0 1 0 0 (0) (4) (0) (0)	<pre></pre>	28> 2 0 0 0 (7) (0) (0) (0)	(34) 4 2 0 0 (12) (6) (0) (0)
	cyst	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0)	0 0 0 0 0 (0)	0 1 0 0
	hyaline droplet	0 0 0 0 0 (0) (0)	1 0 0 0 (3) (0) (0)	2 0 0 0 0 (7) (0) (0)	2 1 0 0 (6) (3) (0) (0)
	basophilic change	7 0 0 0 (29) (0) (0) (0)	12 1 0 0 (41) (3) (0) (0)	5 1 0 0 (18) (4) (0) (0)	13 0 0 0 (38) (0) (0) (0)

< a >

a: Number of animals examined at the site

b

b : Number of animals with lesion

(c) c:b/a*100

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

STUDY NO. : 0372

: MOUSE Crj:BDF1

REPORT TYPE : A1

ANIMAL

: FEMALE

4000 ppm 1000 ppm 2000 ppm Control Group Name 34 29 28 No. of Animals on Study

Organ	Findings	Grade 1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)
{Urinary sys	stem)				
kidney	deposit of hemosiderin	<24> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	<pre></pre>	(34) 0 0 0 0 (0) (0) (0) (0)
	hyaline cast	0 1 0 0 (0) (4) (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (4) (0) (0)	0 0 0 0 0 (0) (0)
	lymphocytic infiltration	2 0 0 0 0 (8) (0) (0) (0)	2 0 0 0 0 (7) (0) (0) (0)	1 1 0 0 (4) (4) (6) (6)	i 0 0 0 (3) (0) (0) (0)
	inflammatory polyp	0 2 0 0 (0) (8) (0) (0)	0 2 2 0 (0) (7) (7) (0)	0 0 5 0 * (0) (18) (0)	1 1 1 0 (3) (3) (0)
	hydronephrosis	1 0 1 0 (4) (0) (4) (0)	1 0 4 0 (3) (0) (14) (0)	0 0 5 0 (0) (18) (0)	2 0 2 0 (6) (6) (6) (0)
	papillary necrosis	0 0 0 0 0	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (3) (0) (0)
	mineralization:papilla	1 0 0 0 0 (4) (0) (0) (0)	1 0 0 0 0 (3) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	mineralization:pelvis	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	2 0 0 0 0 (7) (0) (0) (0)	4 0 0 0 (12) (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)

BAIS4

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1
SEX : FEMALE

Organ		p Name	1000 ppm 29 1 2 3 4 (%) (%) (%) (%)	2000 ppm 28 1 2 3 4 (%) (%) (%) (%)	4000 ppm 34 1 2 3 4 (%) (%) (%) (%)
{Urinary syst	tem)				
kidney	mineralization:cortex	<24> 0 0 0 0 0 0 0 0 0	<pre></pre>	<28> 0 0 0 0 0 0 0 0 0 0 0 0	34> 0 0 0 0 (0) (0) (0) (0)
	desquamation:pelvis	1 0 0 0 (4) (0) (0) (0)	5 0 0 0 (17) (0) (0) (0)	4 0 0 0 (14) (0) (0) (0)	3 0 0 0 0
	urothelial hyperplasia:pelvis	0 0 0 0 0 (0)	0 0 0 0 0 (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (3) (0) (0)
{Endocrine s	ystem)				
pituitary	cyst	3 0 0 0 (13) (0) (0) (0)	<29> 4 0 0 0 (14) (0) (0) (0)	<28> 6 0 0 0 (21) (0) (0) (0)	(34) 6 0 0 0 (18) (0) (0) (0)
	hyperplasia	4 6 1 0 (17) (25) (4) (0)	8 2 0 0 (28) (7) (0) (0)	3 1 0 0 (11) (4) (0) (0)	4 0 0 0 ***
thyroid	cystic thyroid follicle	245 2 0 0 0 (8) (0) (0) (0)	29> 1 0 0 0 (3) (0) (0) (0)	(28) 1 0 0 0 (4) (0) (0) (0)	(34) 1 0 0 0 (3) (0) (0) (0)
Grade (a) b (c) Significant	1: Slight 2: Moderate 3: Market a: Number of animals examined at the site b: Number of animals with lesion $c: b / a * 100$ difference; $*: P \le 0.05$ **: $P \le 0.05$				

SACRIFICED ANIMALS (105W)

ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1

STUDY NO. : 0372

SEX	: FEMALE				PAGE: 23
Organ	Findings	Group Name Control No. of Animals on Study 24 Grade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 29 1 2 3 4 (%) (%) (%) (%)	2000 ppm 28 4 (%) (%) (%)	4000 ppm 34 1 2 3 4 (%) (%) (%)
{Endocrine s	system)	and the state of t			
adrenal	spindle-cell hyperplasia	6 18 0 0 (25) (75) (0) (0)	<pre></pre>	7 20 1 0 (25) (7i) (4) (0)	24 9 0 0 ** (71) (26) (0) (0)
	hyperplasia:cortical cell	2 0 0 0 0 (8) (0) (0) (0)	0 2 0 0 (0) (7) (0) (0)	1 1 0 0 (4) (4) (0) (0)	0 0 0 0 0 (0) (0)
	focal fatty change:cortex	0 2 0 0 (0) (8) (0) (0)	0 0 0 0 0 (6)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
{Reproductiv	ve system)				
ovary	angiectasis	(24) 0 1 0 0 (0) (4) (0) (0)	<pre></pre>	<pre></pre>	34> 0 0 0 0 (0) (0) (0) (0)
	thrombus	0 0 0 0 0 (0) (0) (0)		0 0 1 0 (0) (4) (0)	0 0 0 0 0 (0) (0)
	cyst	5 2 0 0 (21) (8) (0) (0)		4 1 0 0 (14) (4) (0) (0)	3 2 0 0 (9) (6) (0) (0)
uterus	thrombus	\(\lambda 24 \rangle \) 1		<28> 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<34> 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. : 0372

ANIMAL

: MOUSE Crj:BDF1

REPORT TYPE : A1

: FEMALE

4000 ррп 1000 ppm 2000 ppm Group Name Control 28 34 29 No. of Animals on Study 24 Grade (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) Findings_ {Reproductive system} (29) <28> <34> <24> uterus 19 5 1 0 28 1 0 0 * 4 0 0 19 2 0 0* cystic endometrial hyperplasia (82) (3) (0) (0) (68) (18) (4) (0) (66) (7) (0) (0) (83) (17) (0) (0) 0 0 0 0 0 0 0 0 0 0 1 0 xanthogranuloma (0)(0)(0)(0) (0) (0) (0) (0) (0)(0)(0)(0) (0)(0)(4)(0) <34> (29) <24> vagina 0 0 0 0 2 0 0 0 0 0 0 0 0 0 0 0 epidermal cyst (0)(0)(0)(0) (7)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) <24> <29> mammary gl 0 0 0 0 0 0 0 0 1 0 0 0 0 0 0 0 galactocele (0)(0)(0)(0) (0)(0)(0)(0) (4)(0)(0)(0) (0)(0)(0)(0) {Nervous system} <28> <24> brain 0 0 0 0 1 0 0 0 0 0 0 0 0 0 0 vacuolic change (0)(0)(0)(0) (4)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) 4 0 0 0 3 0 0 0 1 0 0 0 2 0 0 0 mineralization (11) (0) (0) (0) (3)(0)(0)(0) (14) (0) (0) (0) (8) (0) (0) (0)

Grade

1 : Slight

2 : Moderate

3 : Marked

4 : Severe

< a >

a: Number of animals examined at the site

b

b: Number of animals with lesion

(c)

c:b/a * 100

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

(HPT150)

BAIS4

SACRIFICED ANIMALS (105W) : MOUSE Crj:BDF1

STUDY NO. : 0372 REPORT TYPE : A1

ANIMAL

: FEMALE

4000 ppm 1000 ppm 2000 ppm Group Name Control 34 28 No. of Animals on Study 24 29 Grade 3 (%) (%) (%) (%) (%) (%) Findings_ (Special sense organs/appendage) <34> <29> <24> eye 2 0 0 0 0 0 0 0 0 0 0 0 0 0 0 degeneration:cornea (7)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (4)(0)(0)(0) <24> <29> Harder gl 2 0 0 0 0 0 0 0 1 0 0 0 0 0 0 0 hyperplasia (0)(0)(0)(0) (3)(0)(0)(0) (0) (0) (0) (0) (6)(0)(0)(0) {Body cavities} <28> <34> peritoneum 0 0 0 0 0 0 0 0 0 0 0 thrombus (0) (0) (0) (0) (0)(0)(0)(0) (0)(0)(0)(0) (3)(0)(0)(0) Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe

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

b: Number of animals with lesion b

c:b/a * 100 (c)

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

BAIS4

PAGE: 25

(HPT150)

APPENDIX L 5

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOUSE: MALE: DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0372

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

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE

Organ	N	roup Name	500 ppm 12 12 1 2 3 4 (%) (%) (%)	1000 ppm 8 1 2 3 4 (%) (%) (%) (%)	2000 ppm 11 1 2 3 4 (%) (%) (%) (%)
{Integumentar	y system/appandage)				
skin/app	ulcer	<12> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<12> 1 1 0 0 (8) (8) (0) (0)	<pre></pre>	\(\lambda 11 \rangle \) 1
	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 1 0
{Respiratory	system}				
nasal cavit	eosinophilic change:olfactory epitheliu	(12) m 4 1 0 0 (33) (8) (0) (0)	(12> 1 0 0 0 (8) (0) (0) (0)	3 0 0 0 (38) (0) (0) (0)	6 1 0 0 (55) (9) (0) (0)
	eosinophilic change:respiratory epithel	ium 6 0 1 0 (50) (0) (8) (0)	4 1 1 0 (33) (8) (8) (0)	3 1 0 0 (38) (13) (0) (0)	9 0 1 0 (82) (0) (9) (0)
	respiratory metaplasia:olfactory epithe	6 0 0 0 (50) (0) (0)	0 0 0 0 *	2 1 0 0 (25) (13) (0) (0)	3 0 0 0 (27) (0) (0) (0)
	respiratory metaplasia:gland	6 1 0 0 (50) (8) (0) (0)	3 1 0 0 (25) (8) (0) (0)	3 1 0 0 (38) (13) (0) (0)	8 0 0 0 (73) (0) (0) (0)
nasopharynx	eosinophilic change	12> 1 0 0 0 (8) (0) (0) (0)	1 1 0 0 (8) (8) (0) (0)	0 0 0 0 (0) (0) (0) (0)	2 0 0 0 (18) (0) (0) (0)
Grade <a>> b (c) Significant d	1: Slight 2: Moderate 3: a: Number of animals examined at the sit b: Number of animals with lesion c: b / a * 100 ifference; *: P ≤ 0.05 **: P ≤				

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

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE

organ	Findings	Group Name No. of Animals on Study Grade	/ 1 (%)		ol 3 %)	4 (%)		1(%)			pm 3 %)	<u>4</u> (%)	(K)	10 2 (%)		3 (%)	<u>4</u> (%)		<u>1</u> (%)		2000 11 2 (%)	0 ppn 1 3 (%)		4 (%)
Respirator	y system]																									
rachea	eosinophilic change	(1 8) (<1 0 (0)	0 0) (0 (0)	(1 8		0	(0 0) (0 (0)		0 0) (0		0 0)	0 (0)	(I (9)		<11 0 0)	1> 0 (0)		0
ing	congestion	(0 0) (<1 0 (0)	0 0) (0 (0)	(1 8		0		0 0) (0 (0)		0 0) (0	(8>	0	0 (0)	(0 (0)		<1: 0 0)	1> 0 (0)		0
	hemorrhage	(0 0) (0 (0)	0 0) (0 (0)	(0		0 0)		0 0) (0 (0)		2 5) (0	(0 0)	0 (0)	(0 (0)		0 0)	(0)		(
	edema	(1 8) (0 (0)	0 0) (0 (0)	(1 (8	;) (0 0)	(0 0)	0 (0)		0 0) (0 (0)	(0 0)	0 (0)	(0 (0)		1 9)	(0)		0
	inflammatory infiltration	(1 8) (0 (0)	0 0) (0 (0)	(1	i) (0 0)	(0 0)	0 (0)		0 0) (0 (0)	(0 0)	0 (0)	(3 (27)		0 0)	0 (0)		(
	accumulation of foamy cells	(1 8) (0 (0)	0 0) (0 (0)	í	0		0 0)		0 0)	0 (0)		1 3) (0 (0)	(0	0 (0)	(1 (9)) (1 9)	(0) ((
	bronchiolar cell hyperplasia	(0	0 (0)	0 0)	0 (0)	ŧ	0)		0 0)		0 0)	0 (0)		0 0) (0 (0)	(0	0	(1 (9)		0 0)	0 (0)		(
	bronchiolar-alveolar cell hyperplasia		0	0 (0)	0 0)	0		((0 0)		0	0 (0)		0 0) (0 (0)		0	0 (0)	(I (9)		0 0)	0		(

Grade 1 : Slight 2 : Moderate 3 : Marked

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

ь 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

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

 \sim

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1
SEX : MALE

Organ	Group No. of / No. of / Grade Findings	Control Control Control Control Control Control	500 ppm 12 1 2 3 4 (%) (%) (%) (%)	1000 ppm 8 1 2 3 4 (%) (%) (%) (%)	2000 ppm 11 1 2 3 4 (%) (%) (%) (%)
(Nematopoiet)	c system)				
one marrow	decreased hematopoiesis	(12) 0 I 0 0 (0) (8) (0) (0)	(12> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	(11) 0 0 0 0 (0) (0) (0) (0)
	erythropoiesis:increased	0 0 0 0 0 (0) (0)	3 0 0 0 (25) (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0)
	megakaryocyte:increased	2 0 0 0 (17) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0)
spleen	plasma cell hyperplasia	<12> 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 (0) (0) (0) (0)	<pre></pre>	(11) 1 0 0 0 (9) (0) (0) (0)
	extramedullary hematopoiesis	2 0 3 0 (17) (0) (25) (0)	0 1 2 0 (0) (8) (17) (0)	0 1 0 0 (0) (13) (0) (0)	1 0 0 0 0 (9) (0) (0)
(Circulatory	system)				
heart	thrombus	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	<pre></pre>	0 0 1 0 (0) (0) (9) (0)
Grade <a> b (c)	1: Slight 2: Moderate 3: Marke a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100	d 4: Severe			

DEAD AND MORIBUND ANIMALS (0-105W)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE

STUDY NO. : 0372

Organ	Findings	Group Name Control No. of Animals on Study 12	500 ppm 12	1000 ppm 8	2000 ppm 11
		Grade 1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)
Circulatory	system]				
heart	mineralization	<12> 0 0 0 0 (0) (0) (0) (0)	(12> 1 0 0 0 (8) (0) (0) (0)	<pre></pre>	<11> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
	arteritis	1 0 0 0 (8) (0) (0) (0)	1 0 0 0 0 (8) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	dilatation:right ventricle	2 0 0 0 (17) (0) (0) (0)	I 0 0 0 (8) (0) (0) (0)	1 0 0 0 0 (13) (0) (0) (0)	1 0 0 0 0 (9) (0) (0)
Digestive s	ystem}				
stomach	erosion:forestomach	<12> 0 0 0 0 0 0 0 0 0 0 0 0	<12> 0 0 0 0 0 0 0 0 0 0 0	<pre></pre>	(11) 1 0 0 0 (9) (0) (0) (0)
	hyperplasia:forestomach	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (9) (0) (0)
	hyperplasia:glandular stomach	1 0 0 0 0 (8) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0)	0 0 0 0 0 (0)
iver	congestion	<12> 0 0 0 0 (0) (0) (0) (0)	1 0 0 0 (8) (0) (0) (0)	< 8> 0 0 0 0 (0) (0) (0) (0)	<11> 0 0 0 0 0 0 0 0 0 0 0

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

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE

		Group Name No. of Animals on Study Grade 1 (%)	1: 2	3	4_	1	12 2	3	4_	1		1000 8 2		4	<u>_1</u>		2	3	4
rgan	Findings	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%))	(%)	(%)	(%)	(%) ——	(%)	(%)	(%
Digestive sy:	etem)																		
iver	necrosis:central	0 (0)	(0)	0	0 (0)	0 (0) (<1: 0 0 0)	0	0 (0)	0 (0)		0 (0	0	0 (0)	((<1 2 18)	1> 0 (0)	0 (0
	necrosis:focal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 13		0	0 (0)	0 (0)	((1 9)	0 (0)	((
	fatty change:central	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)	((
	granulation	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0		0 0)	0 (0)	0 (0)		2 8) (0 0)	0 (0)	((
	acidophilic cell focus	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	(0		0 0)	0 (0)	0 (0)	(1	2 8) (0	(0)	((
	basophilic cell focus	. (0)	0 (0)	0 (0)	0 (0)	(8)	0 (0)	0 (0)	0 (0)	(0		0 0)	0 (0)	0 (0)		0 0) (0	(0)	()
	bile ductular proliferation	0 (0)	0 (0)	(0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0)))) (0 0)	0 (0)	0 (0)	(-	1 9) (0	(0)	(
gall bladd	hyperplasia	0 (0)		1> 0 (0)	0 (0)	1 (8)	0	2> 0 (0)	0 (0)) ()	0 0)	0	0 (0)		0 0) (0	0 (0)	

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

b b: Number of animals with lesion (c)

c:b/a*100

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

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

ANIMAL : MOUSE Crj:BDF1

STUDY NO. : 0372 REPORT TYPE : A1 SEX : MALE

> 2000 ppm 1000 ppm 500 ppm Group Name Control

		No. of Animals on Study 12	$\begin{matrix}&&12\\1&2&3&4\end{matrix}$	8 1 2 3 4	11 1 2 3 4
Organ	Findings	Grade 1 2 3 4 (%) (%) (%) (%)	$\frac{1}{(\%)}$ $\frac{2}{(\%)}$ $\frac{3}{(\%)}$ $\frac{4}{(\%)}$	(%) (%) (%) (%)	(%) (%) (%) (%)
		4.44			- the control
{Urinary syste	em)				
kidney	hemorrhage	1 0 0 0 (8) (0) (0) (0)	<12> 0 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
	cyst	1 0 0 0 (8) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	hyaline droplet	0 2 0 0 (0) (17) (0) (0)	2 0 0 0 0 (17) (0) (0) (0)	1 1 0 0 (13) (13) (0) (0)	2 0 0 0 (18) (0) (0) (0)
	basophilic change	4 0 0 0 0 (33) (0) (0) (0)	4 0 0 0 (33) (0) (0) (0)	1 0 0 0 0 (13) (0) (0)	6 0 0 0 0 (55) (0) (0) (0)
	deposit of hemosiderin	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (9) (0) (0)
	in[]ammation	0 1 0 0 (0) (8) (0) (0)	1 0 0 0 0 (8) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 (0) (0)
	lymphocytic infiltration	1 0 0 0 (8) (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0) (0)
	inflammatory polyp	0 1 0 0 (0) (8) (0) (0)	0 0 1 0	0 0 1 0 (0) (13) (0)	0 1 0 0 (0) (0)

Grade

^{1 :} Slight

^{2 :} Moderate

^{3 :} Marked

^{4 :} Severe

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

b : Number of animals with lesion b

⁽c) c:b/a*100

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

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

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

galı	No	coup Name Control 0. of Animals on Study 12 rade 1 2 3 4 (%) (%) (%) (%)	500 ppm 12 1 2 3 4 (%) (%) (%) (%)	1000 ppm 8 1 2 3 4 (%) (%) (%) (%)	2000 ppm 11 1 2 3 4 (%) (%) (%) (%)
Jrinary syste	em)				
idney	hydronephrosis	<12> 0 1 1 0 (0) (8) (8) (0)	0 0 0 1 (0) (0) (0) (8)	<pre></pre>	<pre></pre>
	mineralization:pelvis	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (9) (0) (0)
	mineralization:cortex	0 0 0 0 0 (0) (0)	1 0 0 0 0 (8) (0) (0) (0)	3 0 0 0 0 (38) (0) (0) (0)	1 0 0 0 0 (9) (0) (0)
	glomerulosclerosis	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 1 0 (0) (13) (0)	0 0 0 0 0 (0) (0)
rin bladd	dilatation	0 0 1 0 (0) (0) (8) (0)	0 0 3 0 (0) (0) (25) (0)	<pre></pre>	0 0 1 0 (0) (0) (9) (0)
Endocrine sy	stem)				
ituitary	cyst	<12> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<pre></pre>	< 7> 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 (0) (0) (0) (0)
rade a> b	1: Slight 2: Moderate 3: a: Number of animals examined at the sit b: Number of animals with lesion c: b / a * 100	Marked 4 : Severe e			

STUDY NO. : 0372

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

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

Organ	N	oup Name of Animals on Study rade (%)	Control 12 2 3 4 (%) (%) (%)		500 ppm 12 2 3 4 (%) (%) (%)	_1	1000 ppm 8 2 3 4 (%) (%) (%)	2000 ppm 11 1 2 3 4 (%) (%) (%) (%)
(Endocrine s	ystem)							
oituitary	Rathke pouch	0 (0) (<12> 0 0 0 (0) (0) (0)	1 (8) (<12> 0 0 0 0) (0) (0)		< 7> 0 0 0 0) (0) (0)	2 0 0 0 (18) (0) (0) (0)
thyroid	cystic thyroid follicle	0 (0)	<11> 0 0 0 (0) (0) (0)	1 (8) (<12> 0 0 0 0) (0) (0)		< 8> 0 0 0 0) (0) (0)	<11> 0 0 0 0 0 0 0 0 0 0 0
adrenal	spindle-cell hyperplasia	4 (33)	<12> 0 0 0 (0) (0) (0)	0 (0) (<12> 0 0 0 0) (0) (0)		< 8> 0	(11) 1 0 0 0 (9) (0) (0) (0)
	hyperplasia:cortical cell	1 (8)	0 0 0 0 (0) (0)	0 (0) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 (0) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 (0) (0)
{Reproductiv	re system}							
testis	atrophy	0 (0)	<12> 0 0 0 (0) (0) (0)	0 (0) (<12> 0 0 0 0) (0) (0)		< 8> 0 0 0 0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
	mineralization	9 (75)	0 0 0	8 (67) (0 0 0	7 (88) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	8 0 0 0 (73) (0) (0) (0)
Grade (a) b (c)	1: Slight 2: Moderate 3: a: Number of animals examined at the sit b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤							

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

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

5

REPORT TYPE : A1 SEX : MALE

Organ	Findings	Group Name No. of Animals on Study Grade	Control 12 2 3 4 (%) (%) (%)	500 ppm 12 1 2 3 4 (%) (%) (%) (%)	1000 ppm 8 1 2 3 4 (%) (%) (%) (%)	2000 ppm 11 1 2 3 4 (%) (%) (%) (%)
{Reproductive	• system)					
epididymis	spermatogenic granuloma	0 (0) (<12> 0 0 0 (0) (0) (0)	1 0 0 0 (8) (0) (0) (0)	<pre></pre>	(0) (0) (0) (0) (0) (0) (0) (0)
prep/cli gl	duct ectasia	0 (0) (<12> 0 0 0 (0) (0) (0)	<12> 0 0 0 0 0 0 0 0 0 0 0 0	<pre></pre>	0 1 0 0 (0) (9) (0) (0)
{Nervous syst	tem)					
brain	mineralization	2 (17)	<12> 0 0 0 (0) (0) (0)	<12> 0 0 0 0 (0) (0) (0) (0)	3 0 0 0 (33) (0) (0) (0)	<11> 4 0 0 0 (36) (0) (0) (0)
{Special sens	se organs/appendage)					
eye	degeneration:cornea	(8)	<12> 0 0 0 (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	<pre></pre>
Grade < a > b (c)	1: Slight 2: Moderate a: Number of animals examined at the s b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P;					

(HPT150)

BAIS4

APPENDIX L 6

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOUSE: FEMALE: DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

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

ANIMAL : MOUSE Crj:BDF1

STUDY NO. : 0372

SEX : FEMALE

REPORT TYPE : A1

Organ		Group Name No. of Animals on Study Grade(%)	Con 26 2 (%)	3 (%)	<u>4</u> (%)	<u>1</u> (%)	1000 21 2 (%)	3 (%)	<u>4</u> (%)	<u>1</u> (%)		00 ppm 22 3 (%)	4_	1(%)	4 2 (%		3	4 (%)
{Integumentar	y system/appandage]																	
subcutis	hemorrhage	0 (0)	<26 0 (0) (0	0 (0)	0 (0)	<2° 0 (0)	(0)	0 (0)	0 (0)	0	22> 0 (0)	0 (0)	1 (6)	0		0 0) (0
{Respiratory	system)																	
nasal cavit	angiectasis	0 (0)	<26 0 (0) (0	0 (0)	l (5)	〈2 0 (0)	0	0 (0)	0 (0)	0 (0)		0 (0)	0 (0)	0	<16>)) (0 0) (0 0)
	hemorrhage	0 (0)	0 (0) (0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)		0 (0)	0	(())) (0 (0)	0 0)
	eosinophilic change:olfactory epithel:		0 (0)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	3 (14)	0 (0)	0 (0)	0 (0)	4 (25)	((0) (0 (0
	eosinophilic change:respiratory epithe		2 (8)	0 (0)	0 (0)	9 (43)	8 (38)	1 (5)	0 *	9 (41)	11 (50)	0	0 **) (0)			9 6) (1 6) (0 * 0)
	respiratory metaplasia:olfactory epit		0 (0)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)		0 (0)	0		0 0) (0 (0
	respiratory metaplasia:gland	4 (15)	0 (0)	0	0 (0)	6 (29)	0 (0)	0 (0)	0 (0)	10 (45)	0		0 *	8 (50)		0 0) (0 0) (0 * 0)

b

b : Number of animals with lesion

(c) c:b/a*100

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

(HPT150)

BAIS4

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1
SEX : FEMALE

DEAD AND MORIBUND ANIMALS (0-105W)

	Group Name No. of Anima Grade	1 2 3 4	1000 ppm 21 1 2 3 4	2000 ppm 22 1 2 3 4	4000 ppm 16 1 2 3 4 (%) (%) (%) (%)
rgatı	Findings	(%) (%) (%) (%)	(%) (%) (%)	(%) (%) (%) (%)	(%) (%) (%) (%)
Respiratory s	system)				
asopharynx	eosinophilic change	<26> 1 0 0 0 (4) (0) (0) (0)	3 0 0 0 (14) (0) (0) (0)	(22> 1 0 0 0 (5) (0) (0) (0)	<pre></pre>
lung	edema	<26> 0 0 0 0 0 (0) (0) (0)	<21> 0 0 0 0 0 0 0 0 0 0 0	<pre></pre>	1 0 0 0 (6) (0) (0) (0)
	inflammatory infiltration	1 0 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 (0) (0)	2 0 0 0 0 (10) (0) (0)	0 0 0 0 0 (0) (0)
	lymphocytic infiltration	0 0 0 0 0 (0) (0)	1 0 0 0 0 (5) (0) (0)	0 0 0 0 0 (0)	0 0 0 0 0 0 (0) (0)
	bronchiolar-alveolar cell hyperplasia	1 0 0 0 (4) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (6) (6) (0) (0)
{Hematopoietí	c system)				
bone marrow	decreased hematopolesis	26> 1 0 0 0 (4) (0) (0) (0)	<pre></pre>	<22> 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<16> 0 0 0 0 (0) (0) (0) (0)
Grade <a>> b (c) Significant d	1: Slight 2: Moderate 3: Marked a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 lifference; *: P ≤ 0.05 **: P ≤ 0.01 T	4 : Severe			

(HPT150)

BAIS4

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

: FEMALE

	Grade	Animals on Study 26 1 2 3 4 (%) (%) (%) (%)	1000 ppm 21 1 2 3 4 (%) (%) (%) (%)	2000 ppm 22 1 2 3 4 (%) (%) (%) (%) (%)	4000 ppm 16 1 2 3 4 (%) (%) (%) (%)
rgan	Findings	(%) (%) (%) (%)	(4) (5) (6)		(4) (4) (4)
[Hematopoieti	c system)				
oone marrow	myelofibrosis	26> 1 0 0 0 (4) (0) (0) (0)	21> 1 0 0 0 (5) (0) (0) (0)	2 0 0 0 (9) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
	megakaryocyte:increased	1 0 0 0 0 (4) (0) (0)	0 0 0 0 0	0 0 0 0 0 (0) (0)	3 0 0 0 0 (19) (0) (0)
	granulopoiesis:increased	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0)	1 0 0 0 0 (5) (0) (0)	0 0 0 0 0 0 (0) (0)
lymph node	lymphadenitis	<pre></pre>	0 0 0 0 (0) (0) (0) (0)	(22> 1 0 0 0 (5) (0) (0) (0)	<16> 0 0 0 0 0 0 0 0 0 0 0
spleen	atrophy	<pre></pre>	0 0 0 0 (0) (0) (0) (0)	222> 2 0 0 0 (9) (0) (0) (0)	1 0 0 0 (6) (0) (0) (0)
	deposit of hemosiderin	1 0 0 0 0 (4) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (6) (6) (7) (7)
	deposit of melanin	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (5) (0) (0) (0)	1 0 0 0 0 (6) (6) (0) (0) (0)
Grade < a > b (c)	i: Slight 2: Moderate 3: Mark a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100	ed 4: Severe			

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

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

SEX

PAGE: 13 : FEMALE

Organ	Findings	Group Name No. of Animals on Study Grade 1 (%)	Cont 26 2 (%)		<u>4</u> (%)	<u>1</u> (%)		00 ppm 21 3 (%)	4		1 (%)	200 2 2 (%)	0 ppm 2 3 (%)	4_	(<u>1</u> %)	4000 16 2 (%)		<u>4</u> (%)
{Hematopoie	tic system)																		
spleen	extramedullary hematopoiesis	3 (12)	<26. 3 (12) (1	0 (0)	0 (0)	0		0 (0)	(2 9)	4	2> 1 (5)	0 (0)		2 3) (<16: 1 6) (3 (19)	0 (0)
	follicular hyperplasia	0 (0)	0 (0) (0 (0)	0 (0)	0 (0)	0 (0)	(0)	0 (0)	(0	1 (5)	0 (0)	0 (0)		1 6) (0	0 (0)	0 (0)
(Circulator	y system}																		
neart	thrombus	0 (0)	<26 0 (0) (0	0 (0)	0 (0)	0		0 (0)		1 5)	0	22> 0 (0)	0 (0)		0 0) (<16 0 0) (6> 0 (0)	0 (0)
	mineralization	1 (4)	0 (0) (0 (0)	0 (0)	0 (0)	0 (0)	0 (0	0) (0) (0 0)	0 (0)	0	0 (0)	(0 0) (0	0 (0)	0 (0)
	myocardial fibrosis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	(0)	0 (0	0) (0) (1 5)	0 (0)	(0	0 (0)	(0 (0	0	0 (0)	(0)
	arteritis	0 (0)	1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	(() (0)	0 (0)	0 (0)	(0	0 (0)	(0 (0	0 (0)	0 (0)
	dilatation:right ventricle	2 (8)	0 (0)	0 (0)	0 (0)	1 (5)	0)) (O		0 (0)	0 (0)	(0	0	(2 13) (0 0)	0 (0)	(0)

< a >

a : Number of animals examined at the site

b

b: Number of animals with lesion

c:b/a*100

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

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

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

: FEMALE

REPORT TYPE : A1

)rgan	Findings	Group Name No. of Animals on Study Grade	Con 26 2 (%)	3	<u>4</u> (%)	<u>1</u> (%)		00 ppr 21 3 (%)		<u>4</u> %)	(9	6)	2000 22 2 (%)	3 (%)	(%)		1 (%)		000 p 16		(%)
Digestive	system)																				
tomach	ulcer:forestomach	1 (4)	<26 0 (0) (0	0	0 (0)	0	(21> 0 (0		0 0)))) (<22 0 0)	0	0 (0)	(0	0		0 0) (0 0)
	hyperplasia:forestomach	1 (4)	0 (0) (0 (0	0 (0)	(0)) (0 0)		0 0) (0 0)	0 (0)	0 (0)	(0	0 (0)		0 (0
	erosion:glandular stomach	1 (4)	0 (0) (0 (0 0)	0 (0)	0 (0)			0 0)		0 0) (0 0)	0 (0)	0 (0)	(0 0)	(0		0 0) (0
	ulceriglandular stomach	1 (4)	0 (0)	0 (0 0)	0 (0)	0 (0)			0 0)		0 0) (0	0 (0)	0 (0)	(0	(0		0 0) (0 0
liver	angiectasis	1 (4)	<20 1 (4)	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)	1 (4)	0 (0) (0	0 (0)	1 (5	())) (0 0)		1 5) (0 0)	0 (0)	0 (0)	(0 0)	(0		0	0
	fatty change	1 (4)	0 (0)	0 (0) (0 0)	0 (0)	(0			0 0)	(0 0) (0	0 (0)	0 (0)	(0 0)	(0))) (0	0
	degeneration:focal	0 (0)	0 (0)	0 (0) (0 0)	1 (5)	0 (0			0 0)		0 0) (0	0 (0)	0 (0)	(0) ()	0 (0)	0

< a >

b

a : Number of animals examined at the site

b: Number of animals with lesion

c:b/a*100

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

(HPT150)

BAIS4

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

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

gan	Findings	Group Name No. of Animals on Study Grade	2	ntrol 6 3 (%)	<u>4</u> (%)	<u>1</u> (%)	6	1000 21 2 (6)	3 (%)	<u>4</u> (%)	(1	<u>i</u> %)	200 2 2 (%)	0 ppm 2 3 (%)	(%)	(9	<u>1</u>		10 pp 6 3 (%)		4 (%)
igestive :	system)																				
ver	inflammatory infiltration	1 (4		26> 0 (0)	0 (0)	0 (0)		<21> 0 0) (0	0 (0)		0 0) (0	2> 0 (0)	0 (0)		0 0) ((1 0 (0)	16> 0 (0		0 0)
	granulation	1 (4	1	0 (0)	0 (0)	0 (0)	(0 0) (0	0 (0)	(0 0) (0 (0)	0 (0)	0 (0)	(1	2 .3) (0 (0)	(0		0 0)
	inflammatory cell nest	0 (0	0)) (0)	0 (0)	0 (0)	0	(0 0) (0 0)	0 (0)	(2 9) (0 (0)	(0)	0 (0)		0 0) (0 (0)	((0 0)
	clear cell focus		0 0 0)	0 (0)	0 (0)	0		0 0) (0 0)	0 (0)		1 5) (0 (0)	0 (0)	0 (0)		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)		2 13) (2 (13)		0 0) (0 0)
	basophilic cell focus		0 1 0) (4)			0 (0		l 5) (0	0 (0)	(0	0 (0)	(0)	0 (0)	()	2 13) (0 (0)		0 0) (0
	bile ductular proliferation		0 0 0) (0)	0 (0)		0)) (0 0) (0 0)	0 (0)	(1 5)	0 (0)	(0)	0 (0)		0	0 (0)		0 0) (0
	biliary cyst	(1 0	(0)	0 (0)	(0) (0	0	0 (0)	(2 9)	0 (0)	(0)	0 (0)	(1 6)	0 (0)		0 0) (0

Grade

1 : Slight

2 : Moderate

3 : Marked

1 : Severe

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

b: Number of animals with lesion b

(c) c:b/a*100

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

(HPT150)

BAIS4

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

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE

4000 ppm 2000 ppm Control 1000 ppm Group Name 22 16 21 No. of Animals on Study 26 2 3 Grade (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) Findings. Organ_ (Digestive system) <13> ⟨21⟩ <18> ⟨24⟩ gall bladd 0 0 0 0 0 0 0 0 0 0 1 0 0 0 hyperplasia (8)(0)(0)(0) (10) (0) (0) (0) (6)(0)(0)(0) (0)(0)(0)(0) {Urinary system} <21> <26> kidney 0 0 0 0 0 0 1 0 0 0 infarct (0)(0)(0)(0) (5)(0)(0)(0) (0)(0)(0)(0) (4)(0)(0)(0) 0 0 0 0 0 1 0 0 0 0 0 0 cyst (0)(0)(0)(0) (0)(0)(5)(0) (0)(0)(0)(0) (0)(0)(0)(0) 1 4 0 0 0 0 4 8 2 0 5 5 0 0 hyaline droplet (6)(25)(0)(0) (19) (19) (0) (0) (19) (38) (10) (0) (27) (18) (0) (0) 5 0 4 0 0 0 4 0 0 0 4 0 0 0 basophilic change (18) (0) (0) (0) (31) (0) (0) (0) (15) (0) (0) (0) (19) (0) (0) (0) 0 0 0 0 0 2 0 0 0 0 0 0 hyaline cast (0)(0)(0)(0) (0)(0)(0)(0) (0)(10)(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

lymphocytic infiltration

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

(HPT150)

BAIS4

0 0 0 0

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

1 0

(5)(0)(0)(0)

0 0

0 0

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

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

: MOUSE Crj:BDF1 ANIMAL REPORT TYPE : A1 : FEMALE

STUDY NO. : 0372

2000 ppm 4000 ppm Control 1000 ppm Group Name 16 21 22 No. of Animals on Study 26 Grade (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) Findings (Urinary system) ⟨26⟩ <16> kidney 0 0 0 0 3 0 * inflammatory polyp (0)(9)(14)(0) (0)(6)(13)(0) (0)(0)(0)(0) (10) (0) (14) (0) 0 5 0 ** hydronephrosis 0 0 (0)(0)(0)(0) (14) (5) (14) (0) (0)(9)(27)(0) (13) (0) (31) (0) 1 0 0 0 0 0 0 0 0 papillary necrosis (0)(6)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) 0 0 0 0 0 0 0 0 0 0 0 0 0 mineralization:papilla (0)(0)(0)(0) (6)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) 0 mineralization:cortex 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 (4)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) 0 0 dilatation:tubular lumen 1 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) glomerulosclerosis (0)(0)(8)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(6)(0) desquamation:pelvis (0)(0)(0)(0) (10) (0) (0) (0) (9)(5)(0)(0) (13) (0) (0) (0)

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

b b: Number of animals with lesion

(c) c : b / a * 100

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

(HPT150)

BATS4

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

STUDY NO. : 0372

: MOUSE Crj:BDF1

ANIMAL REPORT TYPE : A1 : FEMALE

4000 ррт 2000 ppm 1000 ppm Control Group Name 22 16 26 21 No. of Animals on Study Grade (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) Organ_ Findings {Urinary system} <16> (26> urin bladd 0 0 0 0 0 0 0 1 0 0 0 0 0 0 0 dilatation (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (4)(0)(0)(0) (Endocrine system) <21> . <26> pituitary 0 0 0 0 0 0 0 0 1 0 0 0 0 0 0 0 angiectasis (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(5)(0)(0) 3 0 0 0 2 0 0 0 1 0 0 0 2 0 0 0 cyst (9)(0)(0)(0) (19) (0) (0) (0) (8)(0)(0)(0) (5)(0)(0)(0) 0 0 0 0 0 0 0 0 1 0 0 0 0 0 0 0 hyperplasia (0) (0) (0) (0) (0)(0)(0)(0) (0)(0)(0)(0) (4)(0)(0)(0) <15> <21> <26> thyroid 0 0 0 0 0 0 0 0 1 0 0 0 inflammatory infiltration (0)(0)(0)(0) (0)(0)(0)(0) (5)(0)(0)(0) (0)(0)(0)(0) ⟨22⟩ <16> adrenal <25> <20> 0 0 0 0 0 0 0 0 0 0 0 0 1 0 0 0 hemorrhage (0)(0)(0)(0) (5)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) 2 : Moderate 3 : Marked 4 : Severe 1 : Slight Grade

(IPT150)

BALS4

⁽a) b

a: Number of animals examined at the site

b : Number of animals with lesion

c:b/a*100 (c)

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

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

ANIMAL : MOUSE Crj:BDF1

STUDY NO. : 0372

REPORT TYPE : A1
SEX : FEMALE

PAGE: 19

Orana	No	coup Name Control . of Animals on Study 26 ade 1 2 3 4 (%) (%) (%) (%)	1000 ppm 21 1 2 3 4 (%) (%) (%) (%)	2000 ppm 22 1 2 3 4 (%) (%) (%) (%)	4000 ppm 16 1 2 3 4 (%) (%) (%) (%)
Organ	rindings	(10) (10) (10)	(10) (10) (10)		(10) (10) (10)
{Endocrine	system)				
adrenal	extramedullary hematopoiesis	<25> 0 0 0 0 (0) (0) (0) (0)	20> 2 0 0 0 (10) (0) (0) (0)	1 0 0 0 (5) (0) (0) (0)	<16> 0 0 0 0 0 0 0 0 0 0 0
	spindle-cell hyperplasia	17 6 0 0 (68) (24) (0) (0)	12 6 0 0 (60) (30) (0) (0)	10 12 0 0 (45) (55) (0) (0)	12 2 0 0 (75) (13) (0) (0)
{Reproducti	ive system)				
ovary	angiectasis	<26> 0 1 0 0 (0) (4) (0) (0)	0 0 0 0 (0) (0) (0) (0)	<222> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>
	cyst	3 I 0 0 (12) (4) (0) (0)	2 1 0 0 (10) (5) (0) (0)	0 1 0 0 (5) (0) (0)	0 0 0 0 0 (0)
uterus	cystic endometrial hyperplasia	<pre></pre>	3 0 0 0 (14) (0) (0) (0)	5 0 0 0 0 (23) (0) (0) (0)	<16> 1 0 0 0 (25) (0) (0) (0)
	xanthogranuloma	0 0 1 0 (0) (4) (0)	0 0 0 0 0 (0) (0)	0 0 1 0 (0) (5) (0)	0 0 0 0 0 (0) (0)
Grade <a> b (c) Significan	1: Slight 2: Moderate 3: a: Number of animals examined at the sit b: Number of animals with lesion c: b / a * 100 t difference; *: P ≤ 0.05 **: P ≤				

(HPT150)

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

STUDY NO. : 0372

: MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE

2000 ppm 4000 ppm 1000 ppm Group Name Control 22 16 No. of Animals on Study 21 Grade (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) Organ_ Findings_ {Reproductive system} <16> <21> <26> mammary gl 1 0 0 0 0 0 0 0 0 0 0 0 0 galactocele (0) (0) (0) (0) (0)(0)(0)(0) (6) (0) (0) (0) (4)(0)(0)(0) {Nervous system} brain 0 0 0 0 0 0 0 0 0 0 0 0 mineralization (0) (0) (0) (0) (0)(0)(0)(0) (4)(0)(0)(0) (10) (0) (0) (0) perivascular inflammation 0 0 0 0 (0)(0)(0)(0) (5)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (16) <21> ⟨22⟩ spinal cord 0 0 0 0 0 0 0 0 0 0 0 0 epidermal cyst (0)(0)(0)(0) (5)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (Special sense organs/appendage) ⟨26⟩ eye 0 0 0 2 0 0 0 0 0 0 0 0 0 degeneration:cornea (0)(0)(0)(0) (5)(0)(0)(0) (8)(0)(0)(0) (10) (0) (0) (0) 1 : Slight 2 : Moderate 3 : Marked 4 : Severe Grade a: Number of animals examined at the site < a > ь b: Number of animals with lesion

PAGE: 20

(c)

c:b/a * 100

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

STUDY NO. : 0372

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : MOUSE Crj:BDF1

DEAD AND MORIBUND ANIMALS (0-105W)

REPORT TYPE : A1

SEX : FEMALE

Organ		up Name Control of Animals on Study 26 de 1 2 3 4 (%) (%) (%) (%)	1000 ppm 21 1 2 3 4 (%) (%) (%) (%)	2000 ppm 22 1 2 3 4 (%) (%) (%) (%)	4000 ppm 16 1 2 3 4 (%) (%) (%) (%)
{Special sense	e organs/appendage)				
llarder gl	degeneration	<26> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	<pre></pre>	<pre></pre>
	hyperplasia	0 0 0 0 0 (0)	0 0 0 0 0 (0) (0)	0 1 1 0 (0) (5) (5) (0)	0 1 0 0 (0) (0)
{Musculoskele	tal system)				
muscle	mineralization	(26) 1 0 0 0 (4) (0) (0) (0)	<pre></pre>	<pre></pre>	(0) (0) (0) (0)
{Body cavitie	s)				
pleura	thrombus	(26) 1 0 0 0 (4) (0) (0) (0)	<pre></pre>	<pre></pre>	<16> 0 0 0 0 0 0 0 0 0 0 0 0 0 0
thoracic ca	hemorrhage	(26) 0 1 0 0 (0) (4) (0) (0)	0 0 0 0 (0) (0) (0) (0)	<22> 0 0 0 0 (0) (0) (0) (0)	<16> 0 0 0 0 0 0 0 0 0 0 0
Grade <a>> b (c) Significant of	 a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 	Marked 4: Severe			

(HPT150)

BAIS4

APPENDIX M 1

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

MOUSE: MALE

(2-YEAR STUDY)

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

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE

STUDY NO. : 0372

SEX : MALE PAGE : 1

Time-relatedWeeks	Items	Group Name	Control	500 ppm	1000 ppm	2000 ррт		
0 - 52	NO. OF EXAMINED ANIMALS		0	1	0	1		
						-		
	NO. OF ANIMALS WITH TUMORS		0	0	0	0		
	NO. OF ANIMALS WITH SINGLE TUMORS NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	0		
	NO. OF ANYMALD WITH MOLITIES TOMORO		U	U	U	U		
	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		0	4	1	1		
	NO. OF ANIMALS WITH TUMORS		0	° 3	1	0		
	NO. OF ANIMALS WITH SINGLE TUMORS		0	3	1	0		
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	ō	0		
	NO. OF BENIGN TUMORS		0	1	0	0		
	NO. OF MALIGNANT TUMORS		0	2	1	0		
	NO. OF TOTAL TUMORS		0	3	1	0		
79 - 104	NO. OF EXAMINED ANIMALS		12	7	7	9	······	
	NO. OF ANIMALS WITH TUMORS		10	7	6	9		
	NO. OF ANIMALS WITH SINGLE TUMORS		4	4	2	5		
	NO. OF ANIMALS WITH MULTIPLE TUMORS		6	3	4	4		
	NO. OF BENIGN TUMORS		4	3	5	5		
	NO. OF MALIGNANT TUMORS		13	7	5	. 8		
	NO. OF TOTAL TUMORS		17	10	10	13		
105 - 105	NO. OF EXAMINED ANIMALS		38	38	42	39		
	NO. OF ANIMALS WITH TUMORS		27	34	38	95		
	NO. OF ANIMALS WITH SINGLE TUMORS		13	34 18	38 12	35 13		
	NO. OF ANIMALS WITH MULTIPLE TUMORS		14	16	26	22		
	NO. OF BENIGN TUMORS		28	37	43	40		
	NO. OF MALIGNANT TUMORS		15	20	27	24		
	NO. OF TOTAL TUMORS		43	57	70	64		
(HPTO70)								

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

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

SEX : MALE

PAGE: 2

ime-related Weeks	Items	Group Name	Control	500 ppm	1000 ppm	2000 ppm	
0 - 105	NO. OF EXAMINED ANIMALS		50	50	50	50	
	NO. OF ANIMALS WITH TUMORS		37	44	45	44	
	NO. OF ANIMALS WITH SINGLE TUMORS		17	25	15	81	
	NO. OF ANIMALS WITH MULTIPLE TUMORS		20	19	30	26	
	NO. OF BENTON TUMORS		32	41	48	45	
	NO. OF MALIGNANT TUMORS		28	29	33	32	
	NO. OF TOTAL TUMORS		60	70	81	77	

(HPT070)

BAIS4

APPENDIX M 2

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

MOUSE: FEMALE

(2-YEAR STUDY)

STUDY NO. : 0372 NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS - TIME RELATED

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE

ime-related Weeks	Items	Group Name	Control	1000 ppm	2000 ppm	4000 ppm	
0 - 52	NO. OF EXAMINED ANIMALS		2	í	0	1	
	NO. OF ANIMALS WITH TUMORS				_		
	NO. OF ANIMALS WITH SINGLE TUMORS		1	1	0	1	
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	1 0	
	NO. OF BENIGN TUMORS				•	v	
			0	0	0	0	
	NO. OF MALIGNANT TUMORS	•	l	i	0	1	
	NO. OF TOTAL TUMORS		1	1	0	1	
53 - 78	NO. OF EXAMINED ANIMALS		1	1	4	3	
	NO OF ANIMALO WITH MINOR			-	•	Ÿ	
	NO. OF ANIMALS WITH TUMORS		1	3	4	2	
	NO. OF ANIMALS WITH SINGLE TUMORS		0	3	2	0	
	NO. OF ANIMALS WITH MULTIPLE TUMORS		1	0	2	2	
	NO. OF BENIGN TUMORS		f	0	3	,	
	NO. OF MALIGNANT TUMORS		ī	3		1	
	NO. OF TOTAL TUMORS		2	3	3 6	3 4	
79 - 104	NO. OF EXAMINED ANIMALS		23				
	THE PARTY OF THE P		2.3	16	18	12	
	NO. OF ANIMALS WITH TUMORS		23	16	17	11	
	NO. OF ANIMALS WITH SINGLE TUMORS		13	8	11		
	NO. OF ANIMALS WITH MULTIPLE TUMORS		10	8	6	4 7	
	NO. OF BENIGN TUMORS			_			
	NO. OF MALIGNANT TUMORS		11	7	8	10	
	NO. OF TOTAL TUMORS		23	21	15	9	
	No. of Total Tomore		34	28	23	19	
105 - 105	NO. OF EXAMINED ANIMALS		0.4				
			24	29	28	34	
	NO. OF ANIMALS WITH TUMORS		17	24	25	31	
	NO. OF ANIMALS WITH SINGLE TUMORS		7	11	11	11	
	NO. OF ANIMALS WITH MULTIPLE TUMORS		10	13	14	20	
	NO. OF BENIGN TUMORS		16	0.4	0.77		
			16	24	27	38	
	NO. OF MALIGNANT TUMORS		15	21	17	22	

9

STUDY NO. : 0372

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

5

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

SEX : FEMALE

PAGE: 4

Time-related Weeks	Items	Group Name	Control	1000 ррт	2000 ppm	4000 ppm	
0 - 105	NO. OF EXAMINED ANIMALS		50	50	50	50	
	NO. OF ANIMALS WITH TUMORS		42	44	46	45	
	NO. OF ANIMALS WITH SINGLE TUMORS		21	23	24	16	
	NO. OF ANIMALS WITH MULTIPLE TUMORS		21	21	22	29	
	NO. OF BENIGN TUMORS		28	31	38	49	
	NO. OF MALICNANT TUMORS		40	46	35	35	
	NO. OF TOTAL TUMORS		68	77	73	84	

(HPT070)

BAIS4

APPENDIX N 1

HISTOPATHOLOGICAL FINDINGS: MEOPLASTIC LESIONS: SUMMARY,

MOUSE: MALE: ALL ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

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REPORT TYPE : A1

: MALE

rgan		p Name Control of animals on Study 50	500 ppm 50	1000 ppm 50	2000 ppm 50
Integumentary	system/appandage)				
subcutis	hemangi oma	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)
	histiocytic sarcoma	0 (0%)	1 (2%)	1 (2%)	I (2%)
Respiratory s	ystem)				
lung	bronchiolar-alveolar adenoma	<50> 5 (10%)	<50> 4 (8%)	<50> 5 (10%)	<50> 2 (4%)
	bronchiolar-alveolar carcinoma	9 (18%)	4 (8%)	5 (10%)	5 (10%)
(Hematopoietic	system)				
lymplı node	malignant lymphoma	<50> 7 (14%)	<50> 7 (14%)	<50> 8 (16%)	<50> 9 (18%)
spleen	hemangioma	<50> 0 (0%)	<50> 0 (0%)	<50> 2 (4%)	<50> 0 (0%)
	histiocytic sarcoma	0 (0%)	1 (2%)	0 (0%)	0 (0%)
	malignant lymphoma	0 (0%)	1 (2%)	0 (0%)	1 (2%)
	mastcytoma:malignant	1 (2%)	0 (0%)	0 (0%)	0 (0%)
	hemangiosarcoma	1 (2%)	0 (0%)	1 (2%)	0 (0%)
{Digestive sys	tem)				
salivary gl	histiocytic sarcoma	<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1 HISTOPATHOLOGICAL FINDINGS: NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

 \bigcirc

REPORT TYPE : A1
SEX : MALE

rgan	Findings	Group Name No. of animals on Study	Co	ntrol 50	50	00 ppm 50	100	00 ppm 50	200	00 ppm 50
igestive sys	tem)									
tomach	carcinoid tumor			<50> (2%)	0	<50> (0%)	0	<50> (0%)	0	<50> (0%)
mall intes	adenoma			<50> (2%)	0	<50> (0%)	0	<50> (0%)	0	<50> (0%)
	histiocytic sarcoma		0	(0%)	1	(2%)	0	(0%)	1	(2%)
liver	hemangioma		6	<50> (12%)	4	<50> (8%)	1	<50> (2%)	0	<50> (0%)
	hepatocellular adenoma		12	(24%)	25	(50%)	34	(68%)	35	(70%)
	histiocytic sarcoma		1	(2%)	1	(2%)	2	(4%)	1	(2%)
	hepatocellular carcinoma		6	(12%)	9	(18%)	12	(24%)	10	(20%)
	hepatoblastoma		1	(2%)	1	(2%)	0	(0%)	1	(2%)
gall bladd	papillary adenoma		0	<46> (0%)	2	<50> (4%)	4	<49> (8%)	5	<47> (11%)
oancreas	islet cell adenoma		0	<50> (0%)	0	<50> (0%)	1	<50> (2%)	0	<50> (0%)
	acinar cell adenocarcinoma		1	(2%)	0	(0%)	0	(0%)	0	(0%)
{Urinary syste	em}									
urin bladd	hemangioma		1	<50> (2%)	0	<50> (0%)	0	<50> (0%)	0	<50> (0%)

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

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE

STUDY NO. : 0372

rgan	Findings	Group Name No. of animals on Study	Control 50	500 ppm 50	1000 ppm 50	2000 ppm 50
Endocrine sys	cem)					
oituitary	adenoma		<48> 1 (2%)	<50> 0 (0%)	<49> 0 (0%)	<50> 0 (0%)
hyroid	C-cell adenoma		<49> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)
idrenal	pheochromocytoma		<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)
{Reproductive	system)					
testis	hemangioma		<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)
	hemangiosarcoma		0 (0%)	1 (2%)	0 (0%)	0 (0%)
epididymis	histiocytic sarcoma		<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)	<50> 1 (2%)
prep/cli gl	xanthoma		<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)
Nervous syste	n)					
spinal cord	histiocytic sarcoma		<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)	<50> i (2%)
periph nerv	histiocytic sarcoma		<50> 0 (0%)	<50> 1 (2%)	<50> 1 (2%)	<50> 1 (2%)
{Special sense	organs/appendage)					
Harder gl	adenoma		<49> 3 (6%)	<50> 4 (8%)	<50> 1 (2%)	<50> 1 (2%)

⁽HPT085)

STUDY NO. : 0372 ANIMAL

: MOUSE Crj:BDF1

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1

SEX : MALE

2000 ppm 50 1000 ppm 500 ppm Group Name Control 50 No. of animals on Study 50 50 Organ_ Findings_ {Special sense organs/appendage} (49> ⟨50⟩ ⟨50⟩ <50> llarder gl 0 (0%) 1 (2%) 1 (2%) 0 (0%) adenocarcinoma (Musculoskeletal system) <50> <50> <50> <50> bone 0 (0%) 0 (0%) 0 (0%) 1 (2%) osteosarcoma (Body cavities) ⟨50⟩ ⟨50⟩ <50> <50> peritoneum 0 (0%) 0 (0%) 0 (0%) 1 (2%) hemangioma < a > a : Number of animals examined at the site b (c) b: Number of animals with neoplasm c:b/a * 100

(IIPT085)

BAIS4

APPENDIX N 2

HISTOPATHOLOGICAL FINDINGS: NEOPLASTIC LESIONS: SUMMARY,

MOUSE: FEMALE: ALL ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1 HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY) ALL ANIMALS (0-105W) $\,$

REPORT TYPE : A1

: FEMALE

rgan	Findings Group No. of	Name C animals on Study	ontrol 50	100	0 ppm 50	200	00 ppm 50	400	00 ppm 50
Integumentary	y system/appandage)								
kin/app	squamous cell papilloma	1	<50> (2%)		<50> (0%)	0	<50> (0%)	0	<50> (0%)
ubcutis	hemangioma	1	<50> (2%)		<50> (0%)	0	<50> (0%)	0	<50> (0%)
	carcinoma:NOS	0	(0%)	. 0	(0%)	1	(2%)	0	(0%)
Respiratory s	system)								
asal cavit	chondroma	1	<50> (2%)	0	<50> (0%)	0	<50> (0%)	0	<50> (0%)
	hemangioma	1	(2%)	0	(0%)	0	(0%)	0	(0%)
ung	bronchiolar-alveolar adenoma	1	<50> (2%)	1	<50> (2%)	2	<49> (4%)	1	<50> (2%)
	bronchiolar alveolar carcinoma	1	(2%)	1	(2%)	1	(2%)	1	(2%)
[Hematopoieti	c system)								
oone marrow	hemangioma	1	<50> (2%)	0	<50> (0%)	0	<50> (0%)	0	<50> (0%)
	hemangiosarcoma	1	(2%)	0	(0%)	0	(0%)	0	(0%)
ymph node	malignant lymphoma	22	<50> (44%)	16	<50> (32%)	6	<50> (12%)	3	<50> (6%)
spleen	hemangioma	1	<50> (2%)	0	<50> (0%)	0	<50> (0%)	0	<50> (0%)
(a) (c)	a: Number of animals examined at the site b: Number of animals with neoplasm c:b/a*100								

(HPT085)

BAIS4

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1

SEX : FEMALE

STUDY NO. : 0372

4000 ppm Group Name Control 1000 ppm 2000 ppm 50 50 No. of animals on Study Findings_ {| Ilematopoietic system <50> <50> <50> <50> spleen 0 (0%) 0 (0%) 0 (0%) histiocytic sarcoma 1 (2%) 1 (2%) 1 (2%) 1 (2%) 1 (2%) malignant lymphoma 0 (0%) 0 (0%) 2 (4%) 0 (0%) hemangiosarcoma (Digestive system) ⟨50⟩ ⟨50⟩ <50> <50> stomach 0 (0%) 1 (2%) 0 (0%) squamous cell papilloma 0 (0%) <50> <50> <50> <50> large intes 1 (2%) 1 (2%) 0 (0%) 0 (0%) histiocytic sarcoma <50> <50> <50> <50> liver 2 (4%) 0 (0%) 2 (4%) 3 (6%) hemangioma 34 (68%) 23 (46%) 6 (12%) 22 (44%) hepatocellular adenoma 0 (0%) 0 (0%) 0 (0%) 1 (2%) cholangiocellular adenoma 0 (0%) 2 (4%) 0 (0%) 0 (0%) hepatocholangiocellular adenoma 0 (0%) histiocytic sarcoma 1 (2%) 1 (2%) 1 (2%) 4 (8%) 11 (22%) 17 (34%) hepatocellular carcinoma 0 (0%) 0 (0%) 1 (2%) 0 (0%) hepatoblastoma < a > a: Number of animals examined at the site b (c) b : Number of animals with neoplasm c:b/a*100

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1

SEX FEMALE

rgan	Findings	Group Name No. of animals on Study	Control 50	1000 ppm 50	2000 ppm 50	4000 ppm 50
Digestive sy	stem)					
iver	hepatocholangiocellular carcinoma		<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)
all bladd	papillary adenoma		<47> 0 (0%)	<47> 1 (2%)	<49> 5 (10%)	<45> 3 (7%)
Endocrine sy	rstem)					
oituitary	adenoma		<50> 6 (12%)	<50> 3 (6%)	<50> 1 (2%)	<50> 1 (2%)
	adenocarcinoma		1 (2%)	0 (0%)	0 (0%)	0 (0%)
Reproductive	e system)					
ovary	cystadenoma		<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)
	histiocytic sarcoma		0 (0%)	0 (0%)	0 (0%)	1 (2%)
ıterus	xanthoma		<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)	<50> 2 (4%)
	hemangioma		0 (0%)	1 (2%)	0 (0%)	1 (2%)
	endometrial stromal polyp		3 (6%)	0 (0%)	0 (0%)	0 (0%)
	histiocytic sarcoma		9 (18%)	18 (36%)	10 (20%)	10 (20%)
	endometrial stromal sarcoma		0 (0%)	1 (2%)	1 (2%)	0 (0%)
(a) b (c)	a: Number of animals examined at the site b: Number of animals with neoplasm c: b/a	* 100	U (0%)		1 (2%)	1 (2%) 1 (2%)

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1

SEX : FEMALE

(HPT085)

PAGE: 8

BAIS4

rgan		p Name Co of animals on Study	ontrol 50	1000 ppm 50	2000 ppm 50	4000 ppm 50
Reproductive s	eve tem					
	system)					
ammary gl	adenocarcinoma		<50> (0%)	<50> 0 (0%)	<50> 1 (2%)	<50> 1 (2%)
orep/cli gl	adenocarcinoma		<50> (2%)	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)
Nervous system	n}					
eriph nerv	histiocytic sarcoma	. 1	<50> (2%)	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)
(Special sense	organs/appendage}					
larder gl	adenoma	2	<50> (4%)	<50> 0 (0%)	<50> 3 (6%)	<50> 2 (4%)
{Musculoskeleta	al system}					
oone	osteoma	0	<50> (0%)	<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)
{Body cavities)					
peritoneum	hemangionы	0	<50> (0%)	<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)

APPENDIX O 1

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS,

MOUSE: MALE

(2-YEAR STUDY)

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE: 1

BAIS4

STUDY No. : 0372
ANIMAL : MOUSE Cr.j:BDF1
SEX : MALE

(HPT360A)

a				2222	
Group Name	Control	500 ррт	1000 ррт	2000 ррт	
	SITE : lung				
_	TUMOR : bronchiolar-alveol	ar adenoma			
Tumor rate	F (FO (10 0)	4/50/ 0.0	F/F0/ 10 0)	0/50/ + 0)	
Overall rates(a)	5/50 (10. 0)	4/50 (8. 0)	5/50 (10. 0)	2/50(4.0)	
Adjusted rates(b)	10. 53	10.53	10.64	5. 13	
Terminal rates(c)	4/38(10.5)	4/38(10.5)	3/42(7.1)	2/39(5.1)	
Statistical analysis Peto test					
	P =				
Standard method(d)	•				
Prevalence method(d)	P = 0.8542 P =				
Combined analysis(d)	=				
Cochran-Armitage test(e) Fisher Exact test(e)	P = 0.2903	B - 0 E000	B = 0 6907	D = 0.9100	
LISHEL EXACT TEST(6)		P = 0.5000	P = 0.6297	P = 0.2180	
	SITE : lung				
	TUMOR : bronchiolar-alveol	ar carcinoma			
Tumor rate	Tomore . Dionontoral allege	at outothous			
Overall rates(a)	9/50(18.0)	4/50(8.0)	5/50(10.0)	5/50(10.0)	
Adjusted rates(b)	22. 50	10.53	11.90	12. 82	
Terminal rates(c)	8/38(21.1)	4/38(10.5)	5/42(11.9)	5/39(12.8)	
Statistical analysis	0,000 81.17	1,001 10.07	0/ 12/ 11.0/	0/00/ 12.0/	
Peto test					
Standard method(d)	P =				
Prevalence method(d)	P = 0.8352				
Combined analysis(d)	P =				
Cochran-Armitage test(e)	P = 0.3489				
Fisher Exact test(e)		P = 0.1168	P = 0.1940	P = 0.1940	
		. 0.1100		1 0.1070	
	SITE : lung				
	TUMOR : bronchiolar-alveol	ar adenoma, bronchiolar-alveolar carcinom	a		
Tumor rate					
Overall rates(a)	14/50(28.0)	8/50 (16. 0)	10/50(20.0)	7/50 (14. 0)	
Adjusted rates(b)	32, 50	21.05	21.28	17.95	
Terminal rates(c)	12/38(31.6)	8/38(21.1)	8/42(19.0)	7/39(17.9)	
Statistical analysis					
Peto test					
Standard method(d)	P =				
Prevalence method(d)	P - 0.9331				
Combined analysis(d)	P =				
Cochran-Armitage test(e)	P = 0.1394				
Fisher Exact test(e)		P = 0.1135	P = 0.2415	P = 0.0698	

PAGE: 2

BATS4

STUDY No. : 0372 ANIMAL : MOUSE Crj:BDF1

SEX : MALE

(IIPT360A)

Group Name Control 500 ppm 1000 ppm 2000 ppm SITE : lymph node TUMOR : malignant lymphoma Tumor rate 7/50 (14.0) 8/50(16.0) 9/50(18.0) Overall rates(a) 7/50 (14.0) Adjusted rates(b) 10.53 10.53 16, 67 15.38 Terminal rates(c) 4/38(10.5) 4/38 (10.5) 7/42(16.7) 6/39(15.4) Statistical analysis Peto test Standard method(d) P = 0.5231Prevalence method(d) P = 0.2215Combined analysis (d) P = 0.2837Cochran-Armitage test(e) P = 0.5303Fisher Exact test(e) P = 0.6129P = 0.5000P = 0.3929SITE : spleen TUMOR : hemangioma, hemangiosarcoma Tumor rate 1/50(2.0) 3/50(6.0) 0/50(0.0) Overall rates(a) 0/50(0.0) Adjusted rates(b) 0.0 0.0 6.67 0.0 0/38(0.0) Terminal rates(c) 0/38(0.0) 2/42(4.8) 0/39(0.0) Statistical analysis Peto test P = 0.9070 ? Standard method(d) Prevalence method(d) P = 0.3765Combined analysis(d) P = 0.6154Cochran-Armitage test(e) P = 0.7327Fisher Exact test(e) P = 0.5000P = 0.3087P = 0.5000SITE : liver TUMOR : hemangioma Tumor rate Overall rates(a) 6/50 (12.0) 4/50(8.0) 1/50(2.0) 0/50(0.0) Adjusted rates(b) 12.50 7.89 2.38 0.0 Terminal rates(c) 4/38(10.5) 3/38(7.9) 1/42(2.4) 0/39(0.0) Statistical analysis Peto test Standard method(d) P = 0.5895Prevalence method(d) P - 0.9986 Combined analysis (d) P = 0.9987Cochran-Armitage test(e) P = 0.0055**Fisher Exact test(e) P = 0.3703P = 0.0559P = 0.0133*

5

STUDY No. : 0372 ANIMAL : MOUSE Crj:BDF1

: MALE

(HPT360A)

2000 ppm 1000 ррт 500 ppm Control Group Name SITE : liver TUMOR : hepatocellular adenoma Tumor rate 35/50(70.0) 34/50 (68.0) 25/50 (50.0) 12/50 (24.0) Overall rates(a) 80.00 76.74 60.53 Adjusted rates(b) 31.58 31/39(79.5) 32/42(76.2) 23/38(60.5) 12/38(31.6) Terminal rates(c) Statistical analysis Peto test P = ----Standard method(d) Prevalence method(d) P < 0.0001** Combined analysis (d) P = ----P < 0.0001** Cochran-Armitage test(e) P < 0.0001** P < 0.0001** P = 0.0062**Fisher Exact test(e) SITE : liver TUMOR : hepatocellular carcinoma Tumor rate 10/50(20.0) 12/50(24.0) 9/50 (18.0) 6/50 (12.0) Overall rates(a) 26.19 20.9318.60 7.89 Adjusted rates(b) 8/39 (20.5) 11/42(26.2) 7/38 (18.4) 3/38(7.9) Terminal rates(c) Statistical analysis Peto test P = 0.8251Standard method(d) Prevalence method(d) P = 0.0668P = 0.1722Combined analysis (d) P = 0.3097Cochran-Armitage test(e) P = 0.2070P = 0.0961P = 0.2883Fisher Exact test(e) SITE : liver TUMOR : hepatocellular adenoma, hepatocellular carcinoma Tumor rate 38/50 (76.0) 39/50 (78.0) 29/50 (58.0) 18/50(36.0) Overall rates(a) 85.00 86.05 65.79 39.47 Adjusted rates(b) 33/39(84.6) 25/38 (65.8) 36/42(85.7) 15/38(39.5) Terminal rates(c) Statistical analysis Peto test P = 0.8251Standard method(d) P < 0.0001** Prevalence method(d) Combined analysis (d) P < 0.0001** P < 0.0001** Cochran-Armitage test(e) P = 0.0001**P < 0.0001** P = 0.0223*Fisher Exact test(e)

BATS4

STUDY No. : 0372

ANIMAL : MOUSE Crj:BDF1

: MALE

2000 ppm 1000 ppm 500 ppm Group Name Control SITE : gall bladder TUMOR : papillary adenoma Tumor rate 5/47(10.6) 4/49(8.2) 2/50(4.0) 0/46(0.0) Overall rates(a) 13.89 5, 26 9.76 0.0 Adjusted rates(b) 5/36(13.9) 4/41(9.8) 2/38(5.3) 0/35(0.0) Terminal rates(c) Statistical analysis Peto test P = -----Standard method(d) P = 0.0125*Prevalence method(d) P = ----Combined analysis(d) P = 0.0223*Cochran-Armitage test(e) P = 0.0295*P = 0.2686P = 0.0666Fisher Exact test(e) SITE : Harderian gland TUMOR : adenoma Tumor rate 1/50(2.0) 4/50(8.0) 1/50(2.0) 3/49(6.1) Overall rates(a) 2.38 2.569.52 8.11 Adjusted rates(b) 1/39(2.6) 1/42(2.4) 3/37(8.1) 3/38(7.9) Terminal rates(c) Statistical analysis Peto test Standard method(d) Prevalence method(d) P = 0.9045Combined analysis(d) P = -----P = 0.1783Cochran-Armitage test(e) P = 0.3010P = 0.3010P = 0.5114Fisher Exact test(e)

(HPT360A)

BAIS4

STUDY No. : 0372

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANIMAL : MOUSE Crj:BDF1

SEX : MALE

Group Name	Control	500 ppm	1000 ррт	2000 թ. ասա	
	SITE : Harderian gland				
	TUMOR : adenoma, adenocarcinoma				
Tumor rate					
Overall rates(a)	3/49 (6.1)	5/50(10.0)	2/50(4.0)	1/50(2.0)	
Adjusted rates(b)	8. 11	11. 90	4. 76	2. 56	
Terminal rates(c)	3/37(8.1)	4/38 (10. 5)	2/42(4.8)	1/39(2,6)	
Statistical analysis					
Peto test					
Standard method(d)	P =				
Prevalence method(d)	P = 0.9048				
Combined analysis(d)	P =				
Cochran-Armitage test(e)	P = 0.1827				
Fisher Exact test(e)		P = 0.3689	P = 0.4903	P = 0.3010	
(HPT360A)					BAIS

PAGE:

- (a): Number of tumor-bearing animals/number of animals examined at the site.
- (b): Kaplan-Meire estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.
- (c): Observed tumor incidence at terminal kill.
- (d): Beneath the control incidence are the P-values associated with the trend test.

Standard method : Death analysis

Prevalence method: Incidental tumor test

Combined analysis: Death analysis + Incidental tumor test

- (e): The Cochran Armitage and Fisher exact test compare directly the overall incidence rates.
- ?: The conditional probabilities of the largest and smallest possible out comes can not estimated or this P-value is beyond the estimated P-value.

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

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

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

STUDY No. : 0372

ANIMAL : MOUSE Crj:BDF1

EX : MALE

2000 ppm 1000 ppm 500 ppm Control Group Name SITE : ALL SITE TUMOR : hemangioma Tumor rate 1/50(2.0) 3/50(6.0) 5/50 (10.0) 7/50 (14.0) Overall rates(a) 2.27 6.67 10.53 14.58 Adjusted rates(b) 0/39(0.0) 2/42(4.8) 4/38(10.5) Terminal rates(c) 4/38(10.5) Statistical analysis Peto test P = 0.5895Standard method(d) Prevalence method(d) P = 0.9894P = 0.9910Combined analysis(d) P = 0.0220*Cochran-Armitage test(e) P = 0.0297*P = 0.1589P = 0.3798Fisher Exact test(e) SITE : ALL SITE TUMOR : histiocytic sarcoma Tumor rate 6/50(12.0) 6/50(12.0) 5/50 (10.0) 1/50(2.0) Overall rates(a) 7, 69 4.76 5.26 2.50 Adjusted rates(b) 3/39(7.7) 2/42(4.8) 2/38(5.3) 0/38(0.0) Terminal rates(c) Statistical analysis Peto test P = 0.1241Standard method(d) Prevalence method(d) P = 0.1601Combined analysis(d) P = 0.0639P = 0.1125Cochran-Armitage test(e) P = 0.0559P = 0.0559P = 0.1022Fisher Exact test(e)

(HPT360A)

BAIS4

STUDY No. : 0372

ANIMAL : MOUSE Crj:BDF1

: MALE

1000 ppm 2000 ppm 500 ppm Control Group Name SITE : ALL SITE TUMOR : malignant lymphoma Tumor rate 10/50(20.0) 8/50 (16.0) 8/50(16.0) Overall rates(a) 7/50 (14.0) 17.95 16.67 10.53 Adjusted rates(b) 10.53 7/39(17.9) 7/42(16.7) Terminal rates(c) 4/38(10.5) 4/38(10,5) Statistical analysis Peto test P = 0.5836Standard method(d) Prevalence method(d) P = 0.1371Combined analysis(d) P = 0.2313Cochran-Armitage test(e) P = 0.4208P = 0.5000P = 0.2977Fisher Exact test(e) P = 0.5000BA1S4 (HPT360A)

PAGE: 2

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

(b): Kaylan-Meire estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.

(c): Observed tumor incidence at terminal kill.

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

Standard method : Death analysis

Prevalence method: Incidental tumor test

Combined analysis: Death analysis + Incidental tumor test

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

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

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

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

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

APPENDIX O 2

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS,

MOUSE: FEMALE

(2-YEAR STUDY)

PAGE: 6

BAIS4

STUDY No. : 0372

(HPT360A)

ANIMAL : MOUSE Crj:BDF1
SEX : FEMALE

A I DIMINID				
Group Name	Control	1000 руш	2000 թրա	4000 րրա
	SITE : lung			
	TUMOR : bronchiolar-alveolar aden	oma, bronchiolar—alveolar carcinoma		
umor rate	2/50/ 4.0)	9/50/ 4.0)	2/40(6.1)	2/50(4.0)
Overall rates(a)	2/50 (4. 0) 8. 33	2/50 (4. 0) 4. 76	3/49 (6. 1) 4. 26	5.88
Adjusted rates(b) Terminal rates(c)	2/24(8.3)	0/29(0.0)	1/28(3.6)	2/34(5.9)
itatistical analysis	2/24(6.5)	0/29(0.0)	1/20(3.0)	2/34(3.3)
Peto test				
Standard method(d)	P = 0.4318			
Prevalence method(d)	P = 0.4969			
Combined analysis(d)	P = 0.4839			
Cochran-Armitage test(e)	P = 0.9521			D 0.0040
Fisher Exact test(e)		P = 0.6913	P = 0.4903	P = 0.6913
	SITE : lymph node			
	TUMOR : malignant lymphoma			
fumor rate				
Overall rates(a)	22/50 (44.0)	16/50(32.0)	6/50(12.0)	3/50(6.0)
Adjusted rates(b)	37, 50	27, 59	17.86	5. 88
Terminal rates(c)	9/24(37.5)	8/29 (27.6)	5/28(17.9)	2/34(5.9)
Statistical analysis				
Peto test				
Standard method(d)	P = 1.0000			
Prevalence method(d)	P = 0.9992			
Combined analysis(d)	P = 1.0000			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)	•	P = 0.1515	P = 0.0003**	P < 0.0001**
	SITE : liver			
	TUMOR : hemangioma			
Tumor rate				
Overall rates(a)	3/50 (6.0)	2/50(4.0)	0/50(0.0)	2/50(4.0)
Adjusted rates(b)	4. 35	6. 90	0.0	5, 88
Terminal rates(c)	0/24(0.0)	2/29(6.9)	0/28(0.0)	2/34(5.9)
Statistical analysis	• • • • • • • • • • • • • • • • •	_, ,	-, 、,	_,,
Peto test				
Standard method(d)	P = 0.9190 ?			
	P - 0.5992			
Prevalence method(d)				
Prevalence method(d) Combined analysis(d)	P = 0.7575			
	P = 0.7575 P = 0.5583			

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BAIS4

STUDY No. : 0372

(IIPT360A)

ANIMAL : MOUSE Crj:BDF1
SEX : FEMALE

Group Name	Control	1000 թրա	2000 թթա	4000 ppm	
	SITE : liver				
_	TUMOR : hepatocellular aden	oma			
Tumor rate	0 (50 (40 0)	((
Overall rates(a)	6/50 (12. 0)	22/50 (44. 0)	23/50 (46. 0)	34/50(68.0)	
Adjusted rates(b)	21. 43	60.00	62. 07	78. 38	
Terminal rates(c)	5/24(20.8)	17/29 (58.6)	17/28(60.7)	26/34(76.5)	
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)	1 (0.0001**	P = 0.0003**	P = 0.0002**	D / 0 0001++	
DAGO 1651 (C)		r - 0,000577	r - 0.0002**	P < 0.0001**	
	SITE : liver				
	TUMOR : hepatocellular card	inoma			
Tumor rate					
Overall rates(a)	1/50(2.0)	4/50(8.0)	11/50(22.0)	17/50(34.0)	
Adjusted rates(b)	4. 17	11. 11	23. 53	38. 24	
Terminal rates(c)	1/24(4.2)	3/29(10.3)	6/28(21.4)	13/34(38. 2)	
Statistical analysis		.,,	0,00 (02. 2)	10/01(00.2)	
Peto test					
Standard method(d)	P = 0.0687				
Prevalence method(d)	P < 0.0001***				
Combined analysis(d)	P < 0.0001**				
Cochran-Armitage test(e)	P < 0.0001**				
Fisher Exact test(e)		P = 0.1811	P = 0.0019**	P < 0.0001≠≠	
	CTTE . 1:				
	SITE : liver TUMOR : hepatocellular aden	ama basataaallulaa aasataasa			
Tumor rato	Towor + Hebarocerrarat adel	oma, neparocettutar carcinoma			
Overall rates(a)	6/50 (12.0)	23/50 (46.0)	21/50/ 52 0	41 (FO (PO O)	
Adjusted rates(b)	21. 43	23/50 (46. 0) 60. 00	31/50(62.0)	41/50(82. 0)	
Terminal rates(c)	5/24(20. 8)	17/29 (58. 6)	72. 41	89. 47	
Statistical analysis	0/04/ 00.0/	11/29(36.0)	20/28(71.4)	30/34(88. 2)	
Peto test					
Standard method(d)	P = 0.0687				
Prevalence method(d)	P < 0.0001≠≠?				
Combined analysis(d)	P < 0.0001**				
Cochran-Armitage test(e)	P < 0.0001**				
Fisher Exact test(e)	0. 0001	P = 0.0002**	P < 0.0001**	D / 0 000111	
2		1 - 0.0002777	I ✓ U. UUU1↑↑	P < 0.0001**	

PAGE:

BAIS4

STUDY No. : 0372

(HPT360A)

ANIMAL : MOUSE Crj:BDF1 .

SEX : FEMALE

Group Name Control 1000 ppm 2000 ррт 4000 ppm SITE : gall bladder TUMOR : papillary adenoma Tumor rate Overall rates(a) 0/47(0.0) 1/47(2.1) 5/49 (10.2) 3/45(6.7) Adjusted rates(b) 0.0 2.78 14.71 9.38 Terminal rates(c) 0/23(0.0) 0/29(0.0) 4/28(14.3) 3/32(9.4) Statistical analysis Peto test Standard method(d) P = ----Prevalence method(d) P = 0.0600Combined analysis (d) P - -----Cochran-Armitage test(e) P = 0.0818Fisher Exact test(e) P = 0.5000P = 0.0312*P = 0.1130SITE : pituitary gland TUMOR : adenoma Tumor rate Overall rates(a) 6/50(12.0) 3/50(6.0) 1/50(2.0) 1/50(2.0) Adjusted rates(b) 12.50 10.34 3.57 0.0 Terminal rates(c) 3/24(12.5) 3/29 (10.3) 1/28(3.6) 0/34(0.0) Statistical analysis Peto test Standard method(d) P = 0.4259Prevalence method(d) P = 0.9978Combined analysis(d) P = 0.9920Cochran-Armitage test(e) P = 0.0316* Fisher Exact test(e) P = 0.2435P = 0.0559P = 0.0559SITE : pituitary gland TUMOR : adenoma, adenocarcinoma Tumor rate Overall rates(a) 7/50(14.0) 3/50(6,0) 1/50(2.0) 1/50(2.0) Adjusted rates(b) 16.67 10.34 3.57 0.0 Terminal rates(c) 4/24(16.7) 3/29 (10.3) 1/28(3,6) 0/34(0.0) Statistical analysis Peto test Standard method(d) P = 0.4259Prevalence method (d) P - 0.9993 Combined analysis(d) P = 0.9970Cochran-Armitage test(e) P = 0.0157*Fisher Exact test(e) P = 0.1589P = 0.0297*P = 0.0297*

STUDY No. : 0372

ANIMAL : MOUSE Crj:BDF1

SEX : FEMALE

2000 ppm 4000 բբու 1000 ppm Group Name Control SITE : uterus TUMOR : endometrial stromal polyp Tumor rate 0/50(0.0) 3/50(6.0) 0/50(0.0) 0/50(0.0) Overall rates(a) Adjusted rates(b) 8.33 0.0 0.0 0.0 2/24(8.3) 0/29(0.0) 0/28(0.0) 0/34(0.0) Terminal rates(c) Statistical analysis Peto test Standard method(d) P = ----Prevalence method(d) P = 0.9939 ? Combined analysis (d) Cochran-Armitage test(e) P = 0.0389*P = 0.1212P = 0.1212P = 0.1212Fisher Exact test(e) SITE : uterus TUMOR : histiocytic sarcoma Tumor rate 10/50(20.0) 10/50(20.0) Overall rates(a) 9/50(18.0) 18/50 (36.0) Adjusted rates(b) 7.14 25.71 3.57 11.76 4/34(11.8) 1/24(4.2) 6/29 (20.7) 1/28(3.6) Terminal rates(c) Statistical analysis Peto test Standard method(d) P = 0.5960Prevalence method(d) P = 0.7381Combined analysis(d) P = 0.7212Cochran-Armitage test(e) P = 0.6318Fisher Exact test(e) P = 0.0352*P = 0.5000P = 0.5000

PAGE:

(HPT360A) BAIS4

STUDY No. : 0372

SEX

: FEMALE

ANIMAL : MOUSE Crj:BDF1

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE: 10

Group Name	Control	1000 ppm	2000 ррт	4000 ppm	
	SITE : Harderian gland				•
	TUMOR : adenoma				
mor rate					
verall rates(a)	2/50(4.0)	0/50(0.0)	3/50(6.0)	2/50(4.0)	
djusted rates(b)	8. 33	0.0	6,00	5. 41	
erminal rates(c)	2/24(8.3)	0/29(0.0)	1/28(3.6)	1/34(2.9)	
atistical analysis			1, 20 (0.0)	1/34(2.9)	
eto test					
Standard method(d)	P =				
Prevalence method(d)	P = 0.3394				
Combined analysis(d)	P =				
Cochran-Armitage test(e)	P = 0.6489				
Fisher Exact test(e)		P = 0.2475	P = 0.5000	P = 0.6913	

(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.

BAIS4

STUDY No. : 0372 NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANIMAL : MOUSE Crj:BDF1
SEX : FEMALE

Group Name	Control	1000 ррт	muq 0000	4000 թթա	
	SITE : ALL SITE				
	TUMOR : hemangioma				
Tumor rate					
Overall rates(a)	6/50 (12.0)	3/50(6.0)	1/50(2.0)	3/50(6.0)	
Adjusted rates(b)	10, 87	10.34	0.0	8. 82	
Terminal rates(c)	1/24(4.2)	3/29 (10.3)	0/28(0.0)	3/34(8.8)	
Statistical analysis			.,,	7, 7, 0, 0,	
Peto test					
Standard method(d)	P = 0.7385				

PAGE: 3

Terminal rates(c)	1/24(4.2)	3/29 (10.3)	0/28(0.0)	3/34(8.8)	
Statistical analysis					
Peto test					
Standard method(d)	P = 0.7385				
Prevalence method(d)	P = 0.8348				
Combined analysis(d)	P = 0.8852				
Cochran-Armitage test(e)	P = 0.2648				
Fisher Exact test(e)		P = 0.2435	P = 0.0559	P = 0.2435	
	SITE : ALL SITE			,	
	TUMOR : histiocytic sarcoma				
Tumor rate					
Overall rates(a)	12/50 (24. 0)	20/50 (40.0)	13/50(26.0)	11/50(22.0)	
Adjusted rates(b)	7. 50	25. 71	10.71	11. 76	
Terminal rates(c)	1/24(4.2)	6/29(20.7)	3/28(10.7)	4/34(11.8)	
Statistical analysis					
Peto test					
Standard method(d)	P = 0.7657				
Prevalence method(d)	P = 0.7216				
Combined analysis(d)	P = 0.8267				
Cochran-Armitage test(e)	P = 0.3943				
Fisher Exact test(e)		P = 0.0664	P = 0.5000	P = 0.5000	

(HPT360A) BAIS4

STUDY No. : 0372

ANIMAL : MOUSE Crj:BDF1

SEX : FEMALE

Group Name	Control	1000 ppm	2000 թթm	4000 ррт	
	SITE : ALL SITE				
	TUMOR : malignant lymphoma				
`umor rate Overall rates(a) Adjusted rates(b) Terminal rates(c) Statistical analysis	23/50 (46. 0) 37. 50 9/24 (37. 5)	17/50 (34. 0) 31. 03 9/29 (31. 0)	7/50(14. 0) 21. 43 6/28(21. 4)	4/50(8.0) 8.82 3/34(8.8)	
Peto test Standard method(d) Prevalence method(d) Combined analysis(d)	P = 1.0000 P = 0.9976 P = 1.0000				
Cochran-Armitage test(e) Fisher Exact test(e)	P < 0.0001**	P = 0.1537	P = 0.0004**	P < 0.0001**	

PAGE: 4

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

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

(c): Observed tumor incidence at terminal kill.

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

Standard method : Death analysis

Prevalence method : Incidental tumor test

Combined analysis: Death analysis + Incidental tumor test

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

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

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

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

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

APPENDIX P 1

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY,

MOUSE: MALE: ALL ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1 HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1

SEX : MALE

PAGE: I

	•	Group Name No. of Animals on Study	Control 50	500 ppm 50	1000 ppm 50	2000 ppm 50
)rgan	Findings					
fra .						
(Respiratory s	system)					
nasal cavit	leukemic cell infiltration		<50> 1	<50> 1	<50> 0	<50>
	metastasis:liver tumor		i	0	0	0
	metastasis:subcutis tumor		0	0	1	0
	metastasis:periphoral norve tumor		0	0	1	0
	metastasis:epididymis tumor		0	0	0	1
lung	leukemic cell infiltration		<50> 2	<50> 4	<50> 2	<50> 3
	metastasis:liver tumor		4	3	3	2
	metastasis:pancreas tumor		1	0	0	0
	metastasis:subcutis tumor		0	0	1	1
{Hematopoieti	c system)					
bone marrow			<50>	<50>	<50>	<50>
	leukemic cell infiltration		4	4	1	0
	metastasis:spleen tumor		0	1	0	0
	metastasis:small intestine tumor		0	0	0	1
lymph node	leukemic cell infiltration		<50> 0	<50>	<50> 0	<50> 0
	requents sell lutilitization		U	1	V	U
spleen	loukemic cell infiltration		<50> 4	<50> 7	<50> 4	<50> 7
(a)	a: Number of animals examined at the s b: Number of animals with lesion	ite	•			

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

PAGE: 2

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

STUDY NO. : 0372

SEX : MALE

(JPT150)

500 ppm 1000 ppm 2000 ppm Group Name Control 50 50 50 No. of Animals on Study 50 Organ_ Findings_ (Hematopoietic system) ⟨50⟩ <50> <50> <50> spleen 0. metastasis:liver tumor 0 0 i metastasis: small intestine tumor {Circulatory system} ⟨50⟩ <50> <50> <50> heart 2 leukemic cell infiltration 2 0 1 metastasis:liver tumor {Digestive system} <50> ⟨50⟩ <50> <50> tongue 0 0 leukemic cell infiltration 1 <50> <50> <50> salivary gl leukemic cell infiltration 0 0 <50> <50> stomach <50≻ <50> leukemic cell infiltration 1 0 0 <50> <50> <50> <50> small intes leukemic cell infiltration 2 3 0 0 0 metastasis:pancreas tumor <50> <50> <50> <50> large intes leukemic cell infiltration 0 <50> <50> <50> <50> liver leukemic cell infiltration 3 2 1 < a > a : Number of animals examined at the site b: Number of animals with lesion b BAIS4 HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY) ALL ANIMALS (0-105W)

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

b : Number of animals with lesion

STUDY NO. : 0372

		Group Name No. of Animals on Study	Control 50	500 ppm 50	1000 ppm 50	2000 ppm 50
rgan	Findings				10.11	
Digestive sys	stem)					
iver			<50>	<50> 0	<50>	<50>
	metastasis:subcutis tumor		0	0	0	0
	metastasis:spleen tumor metastasis:salivary gland tumor		0	0	1	0
oancreas	leukemic cell infiltration		<50> 0	<50> 0	<50> 0	<50>
	metastasis:spleen tumor		0	1	0	0
{Urinary syst	.em)					
Kidney	leukemic cell infiltration		<50> 2	<50> 3	<50> 1	<50> 1
ırin bladd	leukemic cell infiltration		<50> 1	<50> 1	<50> 0	<50> 0
	metastasis:liver tumor		0	1	0	0
{Endocrine sy	ystem)					
pituitary	metastasis:peripheral nerve tumor		<50> 0	<50> 0	<50> 0	<50> 1
adrenal	leukemic cell infiltration		<50> 0	<50> 2	<50> 0	<50> 0
{Reproductive	e system)					
testis	metastasis:subcutis tumor		<50> 0	<50> 0	<50> 1	<50> 0

⁽JPT150)

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY) ALL ANIMALS (0-105W) STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1
SEX : MALE

Reproductive sys pididymis n somin ves prostate	Findings	No. of Animals on Study	<50> 1 0 0 <50> 0 <50> 0	<50> 1 0 0 <50> 2	<50> 0 1 1 <50> 0	<50> 0 0 0 0 <50>
pididymis n semin ves prostate mammary gl	leukemic cell infiltration metastasis:subcutis tumor metastasis:peripheral nerve tumor leukemic cell infiltration		1 0 0 0 <50> 0	1 0 0 <50>	0 I 1 <50>	0 0 0 <50>
nemmary gl	metastasis:subcutis tumor metastasis:peripheral nerve tumor leukemic cell infiltration		1 0 0 0 <50> 0	1 0 0 <50>	0 I 1 <50>	0 0 0 <50>
nemmary gl	metastasis:subcutis tumor metastasis:peripheral nerve tumor leukemic cell infiltration		1 0 0 0 <50> 0	1 0 0 <50>	1 1 <50>	0 0 <50>
orostate	metastasis:periphoral nerve tumor leukemic cell infiltration		0 <50> 0	0 <50>	1 <50>	0 <50>
ecmin ves prostate nemmary gl	leukemic cell infiltration		<50> 0	<50>	< 50>	<50>
orostate nammary gl	leukemic cell infiltration		0			
orostate	leukemic cell infiltration		•	4	O O	
nammary gl						
папилату gl			<50> 0	<50> 2	<50> 0	<50> 0
nammary gl			0	0	0	1
	metastasts spinar code tamor				/FA\	<50>
(Nervous system)	leukemic cell infiltration		<50> 0	<50> 1	<50> 0	0
	a)					
brain			<50>	<50≻	<50>	<50>
	leukemic cell infiltration		2	i	0	0
	metastasis:peripheral nerve tumor		0	1	I	0
spinal cord			<50>	<50>	<50>	<50>
	leukemic cell infiltration		0	1	0	0
{Special sense of	organs/appendage}					
Harder gl			<50>	<50>	<50>	<50>
	leukemic cell infiltration		2	1	0	0
{Musculoskeleta	al system)					
muscle	leukemic cell infiltration		<50> 0	<50>	<50> 0	<50> 0

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

b: Number of animals with lesion b

(TPT150)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1 HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1
SEX : MALE

		Group Name No. of Animals on Study	Control 50	500 ppm 50	1000 ppm 50	2000 ppm 50
3H	Findings					
dy cavitie	{se					
itoneum			<50>	<50>	<50>	<50>
	metastasis:pancreas tumor		1	0	0	0
a >	a : Number of animals examined at the s. b : Number of animals with lesion	ite				
PT150)						

APPENDIX P 2

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY,

MOUSE: FEMALE: ALL ANIMALS

(2-YEAR STUDY)

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)

ALL ANIMALS (0-105W)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1

STUDY NO. : 0372

SEX : FEMALE

		Group Name No. of Animals on Study	Control 50	1000 ppm 50	2000 ppm 50	4000 ppm 50
organ	Findings					
{Integumentary	system/appandage)					
subcutis			<50>	<50> 0	<50> 0	<50>
	metastasis:uterus tumor		1	U	Ų	1
{Respiratory s	system)					
masal cavit			<50>	<50>	<50>	<50>
	loukemic cell infiltration		0	1	0	0
	metastasis:uterus tumor		0	i	0	0
	metastasis:peripheral nerve tumor		1	0	0	0
lung			<50>	<50>	<50>	<50>
-	leukemic cell infiltration		16	12	2	2
	metastasis:liver tumor		2	3	5	2
	metastasis:uterus tumor		4	5	7	3
	metastasis:preputial/clitoral gland tum	or	1	0	0	0
{Hematopoieti	c system)					
bone marrow			<50>	<50>	<50>	<50>
	leukemic cell infiltration		5	9	3	0
	metastasis:liver tumor		0	1	0	0
	metastasis:uterus tumor		3	3	1	2
lymph node			<50>	<50>	<50>	<50>
	leukemic cell infiltration		0	1	0	0
	metastasis:liver tumor		1	0	0	0

⁽JPT150)

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

ANIMAL : MOUSE Crj:BDF1

STUDY NO. : 0372 REPORT TYPE: A1

(JPT150)

SEX : FEMALE

		Group Name No. of Animals on Study	Control 50	1000 ppm 50	2000 ppm 50	4000 ppm 50
)rgan	Findings					
[Hematopoieti	c system)					
lymph node	metastasis:uterus tumor		<50> 0	<50> 2	<50> 0	<50> 0
	metastasis:large intestine tumor		0	i	0	0
tliymus	metastasis:uterus tumor		<50> 1	<50> 0	<50> 0	<50> 0
spleen	leukemic cell infiltration		<50> 15	<50> 13	<50> 6	<50> 2
	metastasis:liver tumor		0	1	0	0
	metastasis:uterus tumor		5	6	5	2
	metastasis:large intestine tumor		0	1	0	0
{Circulatory	system]					
heart	leukemic cell infiltration		<50> 5	<50> 5	<50> i	<50> 1
	metastasis:uterus tumor		3	0	1	0
{Digostive s	ystem)					
tongue	leukemic cell infiltration		<50> I	<50> 0	<50> 0	<50> 0
salivary gl	leukemic cell infiltration		<50> 3	<50> 5	<50> 2	<50> 0
	metastasis:uterus tumor		0	0	0	1

BAIS4

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)

ALL ANIMALS (0-105W)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE

STUDY NO. : 0372

4000 ppm 2000 ppm 1000 ppm Group Name Control 50 50 50 No. of Animals on Study Findings_ (Digestive system) <50> <50> <50> <50> stomach 0 2 1 0 leukemic cell infiltration <50> <50> <50> <50> small intes 0 leukemic cell infiltration 0 0 1 metastasis:large intestine tumor <50> <50> <50> ⟨50⟩ large intes 0 0 0 leukemic cell infiltration <50> <50> <50> <50> liver 2 leukemic cell infiltration 5 10 7 metastasis:uterus tumor ⟨50⟩ <50> <50> <50> pancreas 3 leukemic cell infiltration 6 1 metastasis:uterus tumor (Urinary system) <50> <50> <50> <50> kidney 6 8 leukemic cell infiltration metastasis:liver tumor 5 metastasis:uterus tumor <50> <50> <50> <50> urin bladd 2 3 leukemic cell infiltration (Endocrine system) <50> <50> ⟨50⟩ <50> pituitary 0 1 leukemic cell infiltration

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

b : Number of animals with lesion

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

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : AI

: FEMALE SEX

2000 ppm 4000 ppm 1000 ppm Group Name Control 50 No. of Animals on Study 50 50 Findings_ (Endocrine system) <50> <50> <50> <50> pituitary 0 0 1 metastasis:uterus tumor <50> <50> <50> <50> thyroid leukemic cell infiltration 0 0 <50> <50> <50> <50> adrenal 0 leukemic cell infiltration 0 0 0 metastasis:uterus tumor (Reproductive system) <50> <50> <50> <50> ovary leukemic cell infiltration 11 1 0 metastasis:liver tumor 5 metastasis:uterus tumor 0 metastasis:large intestine tumor <50> <50> <50> <50> uterus leukemic cell infiltration 4 0 0 0 metastasis:liver tumor 0 metastasis:spleen tumor 0 <50> <50> <50> <50> vagina leukemic cell infiltration 1 <50> <50> <50> <50> mammary gl 0 leukemic cell infiltration 0 0 < a > a : Number of animals examined at the site b b: Number of animals with lesion

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

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE

PAGE: 10

		Group Name No. of Animals on Study	Control 50	1000 ppm 50	2000 ppm 50	4000 ppm 50
rgan	Findings					
Nervous syste	em}					
brain			<50≻	<50>	<50>	<50>
	leukemic cell infiltration		1	4	0	0
	metastasis:uterus tumor		1	1	0	0
pinal cord			<50>	<50>	<50>	<50>
pinai void	leukemic cell infiltration		0	1	0	0
periph nerv			<50>	<50>	⟨50⟩	<50>
or the nor .	leukemic cell infiltration		1	0	0	0
(Special sens	e organs/appendage)					
1950			<50>	<50>	<50>	<50>
eye	metastasis:peripheral nerve tumor		1	0	0	0
larder gl			<50>	<50>	⟨50⟩	⟨50⟩
aroor gr	leukemic cell infiltration		2	3	1	0
	metastasis:peripheral nerve tumor		1	0	0	0
{Musculoskele	etul system)					
muscle			<50>	⟨50⟩	⟨50⟩	<50>
	leukemic cell infiltration		1	0	0	0
{Body cavitie	(ae					
peritoneum			<50>	<50≻	<50>	<50>
Poz I solioum	leukemic cell infiltration		3	1	0	0
(a)	a: Number of animals examined at the sib: Number of animals with lesion	ite				
(JPT150)						

APPENDIX P 3

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY,

MOUSE: MALE: SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)

PAGE: 1

SACRIFICED ANIMALS (105W)

REPORT TYPE : A1
SEX : MALE

: MALE

organ		Group Name No. of Animals on Study	Control 38	500 ppm 38	1000 ppm 42	2000 ppm 39
Respiratory s						
nespiratory s	ystem					
nasal cavit	leukemic cell infiltration		<38> 1	<38> 0	<42> 0	<39> 1
	metastasis:epididymis tumor		0	0	0	1
ung	leukemic cell infiltration		<38> 2	<38> 1	<42> 2	<39> 1
	metastasis:liver tumor		2	1	3	1
	metastasis:subcutis tumor		0	0	0	1
{Hematopoietic	c system)					
bone marrow	leukemic cell infiltration		<38> 2	<38> 2	<42>	<39> 0
spleen	leukemic cell infiltration		<38> 3	<38> 4	<42> 4	<39> 4
{Circulatory s	system)					
heart	leukemic cell infiltration		<38> 0	<38> 1	<42> 0	<39>
{Digestive sys	stem)					
tongue	leukemic cell infiltration		<38> 0	<38> 1	<42> 0	<39> 0
sulivary gl	leukemic cell infiltration		<88> 1	<38> 1	<42> 0	<39>
(a)	a: Number of animals examined at the s b: Number of animals with lesion	ite				
(JPT150)	D. Mainter of alliants with resion					

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

PAGE: 2

BATS4

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1

SEX : MALE

(JPT150)

Organ	Findings	Group Name No. of Animals on Study	Control 38	500 ppm 38	1000 ppm 42	2000 ppm 39
		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1				
{Digestive sy	stem)					
stomach	leukemic cell infiltration		<38> 1	<38> 0	<42> 0	<39> 0
small intes	leukemic cell infiltration		<38> 0	<38> 1	<42> 2	<39> 2
large intes	leukemic cell infiltration		<38> 1	<38> 0	<42> 0	<39> 0
liver	leukemic cell infiltration		<38> 2	(38)	<42> 2	<39> 1
{Urimary syst	tem)					
kidney	leukewic cell infiltration		<38> 1	<38> 1	<42> 1	<39> 1
urin bladd	leukemic cell infiltration		<38> 1	<38> 0	<42> 0	<39>
{Endocrine sy	vstem)					
pituitary	metastasis:peripheral nerve tumor		<38> 0	<38> 0	<42> 0	<39> 1
{Reproductive	e system)					
epididymis	leukemic cell infiltration		<38>	<38> 0	<42> 0	<39> 0
semin ves	leukemic cell infiltration		0 <38>	(38) 1	<42> 0	<39> 0
< a > b	a: Number of animals examined at the b: Number of animals with lesion	e site				

STUDY NO. : 0372
ANIMAL : MOUSE Cr.j:BDF1
REPORT TYPE : A1

SEX : MALE

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR (SUMMARY)

SACRIFICED ANIMALS (105W)

Organ	N N	roup Name o. of Animals on Study	Control 38	500 ppm 38	1000 ppm 42	2000 ppm 39
{Reproducti	ve system)				•	
prostate	leukemic cell infiltration		<38> 0	<38> 1	<42> 0	<39> 0
{Special se	nse organs/appendage)					
Harder gl	leukomic cell infiltration		<38> 1	<38> 1	<42> 0	<39> 0
{Musculoske	letal system)					
muscle	leukemic cell infiltration		0 0	<38> 1	<42> 0	<39> 0
(a)	a : Number of animals examined at the sit b : Number of animals with lesion	е				
(JPT150)						

APPENDIX P 4

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY,

MOUSE: FEMALE: SACRIFICED ANIMALS

(2-YEAR STUDY)

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1 HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR (SUMMARY)

SACRIFICED ANIMALS (105W)

REPORT TYPE : AI SEX : FEMALE

Organ		Group Name No. of Animals on Study	Control 24	1000 ppm 29	2000 ppm 28	4000 ppm 34
Respiratory	system)					
lung	leukemic cell infiltration		<24> 4	<29> 5	<28>	<34>
	metastasis:liver tumor		1	2	0	1
	metastasis:uterus tumor		0	0	0	1
	metastasis:preputial/clitoral gland tumo	or	1	0	0	0
(Hematopoieti	c system)					
oone marrow	leukemic cell infiltration		<24> 0	<29> 2	<28> 3	<34> 0
lymph node	leukemic cell infiltration		<24> 0	<29> 1	<28> 0	<34> 0
pleen	leukemic cell infiltration		<24> 5	<29>	<28> 5	<34>
	metastasis:uterus tumor		0	0	0	. 2
Circulatory	system)					
ueart	leukemic cell infiltration		<24> 2	<29> 2	<28> 0	<34> 1
{Digestive sy	ystem)					
salivary gl	leukemic cell infiltration		<24> 2	<29> 3	<28> 1	<34> 0
	metastasis:uterus tumor		0	0	0	1

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR (SUMMARY) STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1 SACRIFICED ANIMALS (105W)

REPORT TYPE : A1

: FEMALE

Organ	Findings	Group Name No. of Animals on Study	Control 24	1000 ppm 29	2000 ppm 28	4000 ppm 34
(Digestive sy	stem)					
small intes	leukemic cell infiltration		<24>	<29> 0	<28> 1	<34>
large intes	leukemic cell infiltration		<24>	<29> 1	<28>	<34>
liver			<24>	<29>	⟨28⟩	⟨34⟩
	leukemic cell infiltration metastasis:uterus tumor		2	0	3 1	0
pancreas	leukemic cell infiltration		<24>	<29>	<28> 1	<34>
	metastasis:uterus tumor		0	0	0	1
{Urinary syst	em)					
kidney	leukemic cell infiltration		<24> 1	<29> 2	<28> 2	<34> 1
	metastasis:uterus tumor		0	0	0	1
urin bladd	leukemic cell infiltration		<24> 1	<29> 0	<28> 0	<34> 0
{Endocrine sy	rstem)					
thyroid	leukemic cell infiltration		<24> 0	<29> 1	<28> 0	<34> 0
adrenal	leukemic cell infiltration		<24>	<29>	<28>	<34> 0

(JPT150)

STUDY NO. : 0372

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY) SACRIFICED ANIMALS (105W) $\,$

Organ	Findings	Group Name No. of Animals on Study	Control 24	1000 ppm 29	2000 ррт 28	4000 ppm 34
	411-1	* ******			<u></u>	
{Reproductive	system)					
ovary	leukemic cell infiltration		<24> 1	<29> 2	<28> 0	<3 4> 0
	metastasis:uterus tumor		0	0	1	2
uterus	leukemic cell infiltration	·	<24> 2	<29> 0	<28> 0	<34> 0
mammary gl	leukemic cell infiltration		<24> 0	<29> 0	<28> 1	<34> 0
{Nervous syst	tem)					
brain	leukemic cell infiltration		<24> 0	<29> 3	<28> 0	<34> 0
	metastasis:uterus tumor		0	1	0	0
{Special sens	se organs/appendage)					
Harder gl	leukemic cell infiltration		<24> 0	<29> 1	<28> 0	<34> 0
(a)	a : Number of animals examined at the b : Number of animals with lesion	site				
(JPT150)						

APPENDIX P 5

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY,

MOUSE: MALE: DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY) STUDY NO. : 0372 DEAD AND MORIBUND ANIMALS (0-105W)

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : AI

: MALE

		Group Name No. of Animals on Study	Control 12	500 ppm 12	1000 ppm 8	2000 ppm 11
gan	Findings					
Respiratory s	ystem]					
asal cavit	leukemic cell infiltration		<12> 0	<12>	< 8> 0	0
	metastasis:liver tumor		1	0	0	0
	metastasis:subcutis tumor		0	0	ī	0
	metastasis:peripheral nerve tumor		0	0	1	0
ung			<12>	<12>	< 8>	<11>
	leukemic cell infiltration		0	3	0	2
	metastasis:liver tumor		2	2	0	1
	metastasis:pancreas tumor		1	0	0	0
	metastasis:subcutis tumor		0	0	1	0
Hematopoietic	c system)					
one marrow			<12>	<12>	< 8>	<11>
	leukemic cell infiltration		2	2	0	0
	metastasis:spleen tumor		0	i	0	0
	metastasis:small intestine tumor		0	0	0	1
ymph node	leukemic cell infiltration		<12> 0	<12>	< 8>	<11> 0
				-		-
spleen	leukemic cell infiltration		<12>	<12> 3	< 8> 0	<11> 3
	metastasis:liver tumor		0	1	0	0
(a)	a: Number of animals examined at the s b: Number of animals with lesion	ite				
(JPT150)						

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

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

STUDY NO. : 0372

2000 ppm 1000 ppm 500 ppm Control Group Name 11 12 12 No. of Animals on Study Findings_ Organ_ {|lematopoietic system| <11> 〈 8〉 <12> <12> spleen 0 0 metastasis:small intestine tumor {Circulatory system} <11> < 8> <12> <12> heart 2 leukemic cell infiltration 0 0 0 metastasis:liver tumor (Digestive system) <11> < 8> (12> <12> salivary gl 0 leukemic cell infiltration <11> <12> ⟨8⟩ (12) stomach 0 leukemic cell infiltration <11> < 8> <12> <12> small intes 0 1 leukemic cell infiltration 0 0 1 metastasis:pancreas tumor (11) < 8> <12> <12> large intes 1 0 leukemic cell infiltration (11) < 8> <12> <12> liver 0 0 leukemic cell infiltration 0 metastasis: subcutis tumor metastasis:spleen tumor 0 metastasis:salivary gland tumor

(JPT150)

BAIS4

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

b b: Number of animals with lesion

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

PAGE: 3

BAIS4

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : MALE

(JPT150)

STUDY NO. : 0372

2000 ppm 500 ppm 1000 ppm Group Name Control 11 12 No. of Animals on Study Organ. Findings_ (Digestive system) <11> < 8> <12> <12> pancreas 1 0 leukemic cell infiltration 0 0 i metastasis:spleen tumor {Urinary system} < 8> <11> <12> <12> kidney 0 leukemic cell infiltration **<11>** <12> < 8> <12> urin bladd leukemic cell infiltration 0 0 0 metastasis:liver tumor (Endocrine system) < 8> <11> <12> <12> adrenal 0 0 leukemic cell infiltration {Reproductive system} <11> <12> < 8> <12> testis metastasis: subcutis tumor <11> <12> ⟨8⟩ <12> epididymis leukemic cell infiltration metastasis: subcutis tumor 0 0 metastasis:peripheral nerve tumor (11) <12> < 8> <12> semin ves 0 1 leukemic cell infiltration 0 a: Number of animals examined at the site (a) b: Number of animals with lesion b

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

STUDY NO. : 0372 : MOUSE Crj:BDF1 ANIMAL

REPORT TYPE : A1

: MALE SEX

2000 ppm 500 ppm 1000 ppm Group Name Control 11 No. of Animals on Study 12 12 Organ_ Findings_ {Reproductive system} <11> <12> <12> < 8> prostate 0 leukemic cell infiltration 1 0 0 1 metastasis:spinal code tumor <12> <12> < 8> <11> mammary gl leukemic cell infiltration (Nervous system) < 8> <11> <12> <12> brain leukemic cell infiltration 1 0 metastasis:peripheral nerve tumor <11> < 8> <12> <12> spinal cord leukemic cell infiltration 1 {Special sense organs/appendage} Harder gl <12> <12> < 8> <11> leukemic cell infiltration (Body cavities) <12> <12> < 8> (11) peritoneum 0 metastasis:pancreas tumor < a > a : Number of animals examined at the site b: Number of animals with lesion (JPT150)

BAIS4

APPENDIX P 6

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR: SUMMARY,

MOUSE: FEMALE: DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

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

PAGE: 5

BAIS4

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1
SEX : FEMALE

(JPT150)

o	The late	Group Name No. of Animals on Study	Control 26	1000 ppm 21	2000 ppm 22	4000 ppm 16
rgan	Findings					
{Integumenta	ry system/appandage)					
subcutis	metastasis:uterus tumor		<26>	<21> 0	<22> 0	<16>
{Respiratory	system)					
nasal cavit	leukemic cell infiltration		<26> 0	<21> 1	<22> 0	<16> 0
	metastasis:uterus tumor		0	ı	0	0
	metastasis:peripheral nerve tumor		1	0	0	0
lung	leukemic cell infiltration		<26> 12	<21> 7	<22> 1	<16>
	metastasis:liver tumor		1	1	5	1
	metastasis:uterus tumor		4	5	7	2
{Hematopoiet	ic system)					
bone marrow	leukemic cell infiltration		<26> 5	<21>	<22> 0	<16> 0
	metastasis:liver tumor		0	1	0	0
	metastasis:uterus tumor		3	3	1	2
lymph node	metastasis:liver tumor		<26> 1	<21> 0	<22> 0	<16> 0
	metastasis:uterus tumor		0	2	0	0
	metastasis:large intestine tumor		0	1	0	0

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

ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE

STUDY NO. : 0372

Dec. 100	Findings	Group Name No. of Animals on Study	Control 26	1000 ppm 21	2000 ppm 22	4000 ppm 16
rgan	rindings					
(Hematopoietic	c system)					
	,,		<26>	⟨21⟩	<22>	<16>
thymus	metastasis:uterus tumor		1	0	0	0
spleen			<26>	<21>	<22>	<16>
	leukemic cell infiltration		10	7	1	<u>I</u>
	metastasis:liver tumor		0	1	0	0
	metastasis:uterus tumor		5	6	5	0
	metastasis:large intestine tumor		0	1	0	0
{Circulatory						
	system)				(00)	4165
heart	leukemic cell infiltration		<26>	<21> 3	<22> 1	0 <1e>
	metastasis:uterus tumor		3	0	. 1	0
{Digestive sy	rstem]					
tongue			⟨26⟩	<21>	⟨22⟩	<16>
toligue	leukemic cell infiltration		1	0	0	0
salivary gl			<26>	<21>	⟨22⟩	<16>
	leukemic cell infiltration		1	2	1	0
stomach	7 1 7 77 7774 15		<26>	<21> 2	<22>	<16> 0
	leukemic cell infiltration		•		_	
small intes	leukemic cell infiltration		<26>	<21> 0	<22> 0	<16>
	metastasis:large intestine tumor		0	1	0	0
<a>→	a : Number of animals examined at t	the site				
b	b : Number of animals with lesion					

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

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

REPORT TYPE : A1 SEX : FEMALE

		Group Name No. of Animals on Study	Control 26	1000 ppm 21	2000 ppm 22	4000 ppm 16
Organ	Findings	No. of Miland's on Study				
Digestive sy	stem)					
liver			<26>	<21>	<22>	<16>
	leukemic cell infiltration		7	5	1	1
	metastasis:uterus tumor		7	10	7	5
ancreas			<26>	<21>	⟨22⟩	<16>
4.102 000	leukemic cell infiltration		3	2	1	1
	metastasis:uterus tumor		1	1	2	0
(T))					
(Urinary sys	.em					***
kidney	1 1 1 11 11 6114 41		<26> 7	<21> 4	<22>	<16>
	leukemic cell infiltration		•			
	metastasis:liver tumor		1	0	0	0
	metastasis:uterus tumor		1	5	4	0
ırin bladd			<26>	⟨21⟩	⟨22⟩	<16>
	leukemic cell infiltration		2	2	0	0
{Endocrine s	ystem)					
pituitary			<26>	<21>	⟨22⟩	<16>
pituitaly	leukemic cell infiltration		1	0	0	0
	metastasis:uterus tumor		0	0	0	1
thyroid			<26>	<21>	<22>	<16>
, * • * •	leukemic cell infiltration		1	0	0	0
adrenal			<26>	<21>	<22>	<16>
	leukemic cell infiltration		2	2	0	1
< a >	a: Number of animals examined at t	he site				
b	b: Number of animals with lesion					

⁽JPT150)

STUDY NO. : 0372

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

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

(JPT150)

PAGE: 8

BATS4

Organ	Findings	Group Name No. of Animals on Study	Control 26	1000 ppm 21	2000 ppm 22	4000 ppm 16
6						
(Endocrine sys	stem)					
adrenal	metastasis:uterus tumor		<26> 1	<21> 0	<22> 0	<16> 0
{Reproductive	system)					
ovary	loukomic cell infiltration		<26>	<21>	<22>	<16> 1
	metastasis:liver tumor		1	1	0	0
	metastasis:uterus tumor		5	6	5	3
	metastasis:large intestine tumor		0	1	0	0
uterus	leukemic cell infiltration		<26> 2	<21> 2	<22> 0	<16> 0
	metastasis:liver tumor		0	1	0	0
	metastasis:spleen tumor		1	0	0	0
vagina	leukemic cell infiltration		<26>	<21> 1	<22> 0	0 <16>
{Nervous syst	em)					
brain	leukemic cell infiltration		<26>	<21> 1	<22> 0	0
	metastasis:uterus tumor		1	0	0	0
spinal cord	leukemic cell infiltration		<26> 0	<21> 1	<22> 0	<16>
<a>> b	a : Number of animals examined at the b : Number of animals with lesion	site				

STUDY NO. : 0372 ANIMAL : MOUSE Crj:BDF1

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

 \searrow

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REPORT TYPE : A1
SEX : FEMALE

Organ	Findings	Group Name No. of Animals on Study	Control 26	1000 ppm 21	2000 ppm 22	4000 ppm 16
(Nervous system)						
periph nerv	leukemic cell infiltration		<26>	<21> 0	<22> 0	<16> 0
{Special sense of	organs/appendage)					
еуе	metastasis:peripheral nerve tumor		<26>	<21> 0	<22> 0	<16>
llarder gl	leukemic cell infiltration		<26>	<21> 2	<22> 1	<16>
	metastasis:peripheral nerve tumor		1	0	0	0
{Musculoskeleta	l system)					
muscle	leukemic cell infiltration		<26>	<21> 0	<22> 0	<16> 0
{Body cavities}						
peritoneum	leukemic cell infiltration		<26> 3	<21> 1	<22> 0	<16> 0
<pre>a > b</pre>	a: Number of animals examined at the b: Number of animals with lesion	site			-	
(JPT150)						

APPENDIX Q 1

IDENTITY OF o-PHENYLENEDIAMINE DIHYDROCHLORIDE IN THE 2-YEAR DRINKING WATER STUDY

IDENTITY OF o-PHENYLENEDIAMINE DIHYDROCHLORIDE IN THE 2-YEAR DRINKING WATER STUDY

Test Substance : o-Phenylenediamine Dihydrochloride (Wako Pure Chemical Industries, Ltd.)

Lot No. : PAG0825

1. Spectral Data

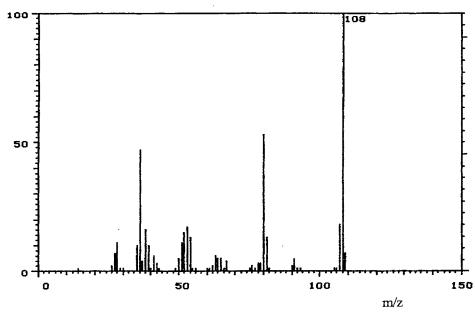
)

Mass Spectrometry

Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance

<u>Determined Value</u> Quasi-molecular ion Peak (m/z) <u>Calculated Value</u> Quasi-molecular ion Peak (m/z)

108

108 (NH₂C₆H₄NH₂·2HCl) - (2HCl)

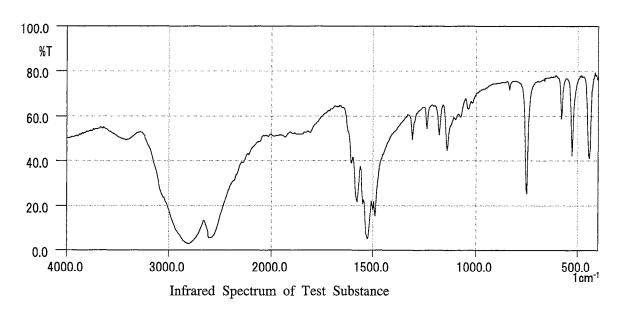
Result: The mass spectrum was consistent with calculated spectrum.

Infrared Spectrometry

Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr

Resolution : 2 cm⁻¹



Literature Values*
Wave Number (cm ⁻¹)
410~ 480
480~ 550
550~ 600
680~ 800
820~ 850
1010~1050
1050~1160
1160~1200
1250~1280
1280~1330
1330~1640
2100~3200

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

2. Conclusion: The test substance was identified as o-phenylenediamine dihydrochloride by mass spectrum and infrared spectrum.

APPENDIX Q 2

STABILITY OF o-PHENYLENEDIAMINE DIHYDROCHLORIDE IN THE 2-YEAR DRINKING WATER STUDY

STABILITY OF o-PHENYLENEDIAMINE DIHYDROCHLORIDE IN THE 2-YEAR DRINKING WATER STUDY

Test Substance

: o-Phenylenediamine Dihydrochloride (Wako Pure Chemical Industries, Ltd.)

Lot No.

: PAG0825

1. Sample

: This lot was used from 1998.12.7 to 2000.12.11. Test substance was stored

in cold storage in a dark place.

2. High Performance Liquid Chromatography

Instrument

: Hewlett Packard 1090 High Performance Liquid Chromatograph

Column

: TSK GEL ODS-80TM (4.6 m ϕ imes 15 cm)

Column Temperature

: Room Temperature

Flow Rate

: 1 mL/min

Mobile Phase

: Distilled Water (10mM Potassium Dihydrogenphosphate, 5mM

1-Hexanesulfonic Acid Sodium Salt): Acetonitrile = 80:20

Detector

: UV (290 nm)

Injection Volume

: 20 µL

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
1998.10.30	1	3.743	100
2000.12.18	1	3.743	100

Result: High performance liquid chromatography indicated one major peak (peak No.1) analyzed on 1998.10.30 and one major peak (peak No.1) analyzed on 2000.12.18. No new trace impurity peak in the test substance analyzed on 2000.12.18 was detected.

3. Conclusion: The test substance was stable for about 26 months in cold storage in a dark place.

APPENDIX Q 3

CONCENTMOUSEION OF o-PHENYLENEDIAMINE DIHYDROCHLORIDE IN FORMULATED WATER IN THE 2-YEAR DRINKING WATER STUDY

CONCENTRATION OF o-PHENYLENEDIAMINE DIHYDROCHLORIDE IN FORMULATED WATER IN THE 2-YEAR DRINKING WATER STUDY

	Male	Male and Female	Male and Female	Female
Date Analyzed	500ª	1000	2000	4000
1998.12.07	507 (101) ^b	1010 (101)	1990 (99.5)	4050 (101)
1999.01.25	515 (103)	964 (96.4)	1920 (96.0)	3880 (97.0)
1999.04.19	515 (103)	1020 (102)	2040 (102)	4080 (102)
1999.07.12	507 (101)	997 (99.7)	1980 (99.0)	4000 (100)
1999.10.04	506 (101)	984 (98.4)	1980 (99.0)	3980 (99.5
1999.12.27	510 (102)	988 (98.8)	2000 (100)	4100 (103)
2000.03.13	498 (99.6)	992 (99.2)	2010 (101)	3920 (98.0
2000.06.05	476 (95.2)	956 (95.6)	1900 (95.0)	3860 (96.5
2000.08.28	481 (96.2)	947 (94.7)	1870 (93.5)	3820 (95.5
2000.10.20	513 (103)	1010 (101)	2040 (102)	4090 (102)

a ppm b %

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

: Hewlett Packard 1090 High Performance Liquid Chromatograph Instrument

: TSK GEL ODS-80TM (4.6 mm ϕ \times 15 cm) Column

Column Temperature : Room Temperature

: 1 mL/min Flow Rate

: Distilled Water (10mM Potassium Dihydrogenphosphate, 5mM 1-Hexanesulfonic Acid Sodium Salt) : Mobile Phase

Acetonitrile = 80 : 20

: UV (290 nm) Detector

: 20 µL Injection Volume

APPENDIX Q 4

STABILITY OF o-PHENYLENEDIAMINE DIHYDROCHLORIDE IN FORMULATED WATER IN THE 2-YEAR DRINKING WATER STUDY

STABILITY OF o-PHENYLENEDIAMINE DIHYDROCHLORIDE IN FORMULATED WATER IN THE 2-YEAR DRINKING WATER STUDY

		Target Concer	ntration
Date Prepared	Date Analyzed	500ª	5000
1998.02.09	1998.02.09	503 (100) ^b	4900 (100)
	1998.02.17°	480 (95.4)	4910 (100)

^a ppm

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

Instrument : Hewlett Packard 1090 High Performance Liquid Chromatograph

Column : TSK GEL ODS-80TM (4.6 mm ϕ × 15 cm)

Column Temperature: Room Temperature

Flow Rate : 1 mL/min

Mobile Phase : Distilled Water (10mM Potassium Dihydrogenphosphate, 5mM 1-Hexanesulfonic Acid

Sodium Salt): Acetonitrile = 80: 20

Detector : UV (290 nm)

Injection Volume : 20 μL

^b % (Percentage was based on the concentration on date of preparation.)

^c Animal room samples

APPENDIX R 1

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS IN THE 2-YEAR DRINKING WATER STUDY OF ρ -PHENYLENEDIAMINE DIHYDROCHLORIDE

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS IN THE 2-YEAR DRINKING WATER STUDY OF o-PHENYLENEDIAMINE DIHYDROCHLORIDE

Item	Method
Hematology	
Red blood cell (RBC)	Light scattering method 1)
Hemoglobin (Hgb)	Cyanmethemoglobin method 1)
Hematocrit (Hct)	Calculated as RBC×MCV/10
Mean corpuscular volume (MCV)	Light scattering method 1)
Mean corpuscular hemoglobin (MCH)	Calculated as Hgb/RBC×10 1)
Mean corpuscular hemoglobin concentration (MCHC)	Calculated as Hgb/Hct×100 1
Platelet	Light scattering method 17
White blood cell (WBC)	Light scattering method 1)
Differential WBC	Pattern recognition method 2)
	(Wright staining)
Biochemistry	
Total protein (TP)	Biuret method 3)
Albumin (Alb)	BCG method 3)
A/G ratio	Calculated as Alb/(TP-Alb) 3)
T-bilirubin	Alkaline azobilirubin method 3)
Glucose	GlcK·G-6-PDH method
T-cholesterol	CE·COD·POD method 3)
Triglyceride	LPL·GK·GPO·POD method 3)
Phospholipid	PLD·ChOD·POD method 3)
Glutamic oxaloacetic transaminase (GOT)	JSCC method 3)
Glutamic pyruvic transaminase (GPT)	JSCC method 3)
Lactate dehydrogenase (LDH)	SFBC method 3)
Alkaline phosphatase (ALP)	GSCC method 3)
γ -Glutamyl transpeptidase (γ -GTP)	L- γ -Glutamyl-p-nitroanilide method ³⁾
Creatine phosphokinase (CPK)	JSCC method 3)
Urea nitrogen	Urease · GLDH method 3)
Sodium	Ion selective electrode method 3)
Potassium	Ion selective electrode method
Chloride	Ion selective electrode method 3)
Calcium	OCPC method 3)
Inorganic phosphorus	PNP·XOD·POD method 3)
Urinalysis	
pH,Protein,Glucose,Ketone body,Occult blood,	Urinalysis reagent paper method 4)
Urobilinogen	

- 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.)
- 4) Ames reagent strips for urinalysis (Uro-Labstix: Bayer Corporation)

APPENDIX R 2

UNITS AND DECIMAL PLACE FOR HEMATOLOGY, AND BIOCHEMISTRY IN THE 2-YEAR DRINKING WATER STUDY OF o-PHENYLENEDIAMINE DIHYDROCHLORIDE

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-YEAR DRINKING WATER STUDY OF o-PHENYLENEDIAMINE DIHYDROCHLORIDE

Item	Unit	Decimal Place
Hematology		
Red blood cell (RBC)	$ imes 10^6 / \mu L$	2
Hemoglobin	g/dL	1
Hematocrit	%	1
Mean corpuscular volume (MCV)	fL	1
Mean corpuscular hemoglobin (MCH)	pg	1
Mean corpuscular hemoglobin concentration (MCHC)	g/dL	1
Platelet	$ imes 10^3 / \mu \mathrm{L}$	0
White blood cell (WBC)	$\times 10^3 / \mu L$	2
Differential WBC	%	0
Biochemistry		
Total protein	g/dL	1
Albumin	g/dL	1
A/G ratio		1
T-bilirubin	mg/dL	2
Glucose	mg/dL	0
T-cholesterol	mg/dL	0
Triglyceride	mg/dL	0
Phospholipid	mg/dL	0
Glutamic oxaloacetic transaminase (GOT)	IU/L	0
Glutamic pyruvic transaminase (GPT)	IU/L	0
Lactate dehydrogenase (LDH)	IU/L	0
Alkaline phosphatase (ALP)	IU/L	0
γ -Glutamyl transpeptidase (γ -GTP)	IU/L	0
Creatine phosphokinase (CPK)	IU/L	0
Urea nitrogen	mg/dL	1
Sodium	mEq/L	0
Potassium	mEq/L	1
Chloride	mEq/L	0
Calcium	mg/dL	1
Inorganic phosphorus	mg/dL	1