1-ブロモブタンのマウスを用いた吸入による2週間毒性試験報告書

試験番号:0481

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APPENDIX A 1

IDENTITY OF 1-BROMOBUTANE IN THE 2-WEEK INHALATION STUDY

IDENTITY OF 1-BROMOBUTANE IN THE 2-WEEK INHALATION STUDY

Test Substance : 1-Bromobutane (Wako Pure Chemical Industries, Ltd.)

Lot No. : ASQ0017

1. Spectral Data

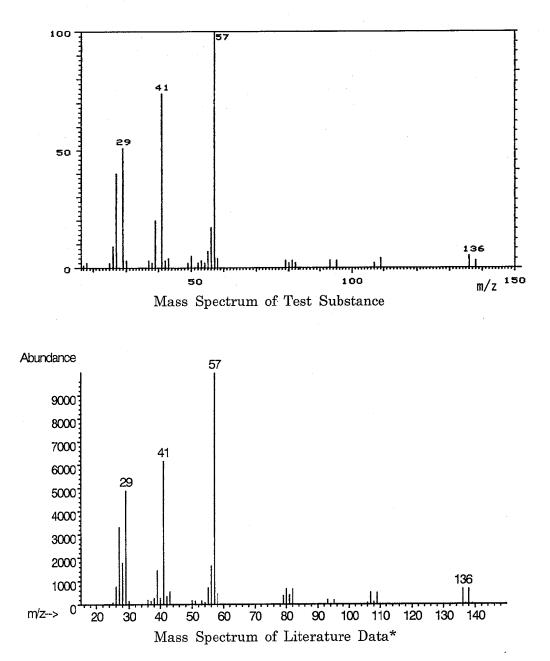
).

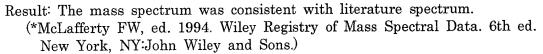
Mass Spectrometry

Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV





500

Wavenumber cm⁻¹

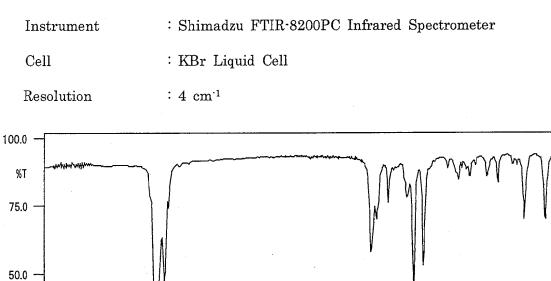
1000

Infrared Spectrometry

3000

25.0

4000

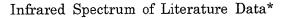


2000

Infrared Spectrum of Test Substance

86.40 **SONULINSING SOULINSONES SOULINSONES**

1500



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

2. Conclusion: The test substance was identified as 1-bromobutane by mass spectrum and infrared spectrum.

APPENDIX A 2

STABILITY OF 1-BROMOBUTANE IN THE 2-WEEK INHALATION STUDY

STABILITY OF 1-BROMOBUTANE IN THE 2-WEEK INHALATION STUDY

Test Substance	: 1-Bromobutane (Wako Pure Chemical Industries, Ltd.)
Lot No.	: ASQ0017
1. Sample	This lot was used from 2003.4.9 to 2003.4.22. Test substance was stored in a dark place at room temperature.
2. Gas Chromatography	7
Instrument	: Hewlett Packard 5890A Gas Chromatograph
Column	: Methyl Silicone (0.53 mm ϕ $ imes$ 60 m)
Column Temperatu	re: 100° C
Flow Rate	: 15 mL/min
Detector	: FID (Flame Ionization Detector)
Injection Volume	:1 μL

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
2003.03.19	1	4.139	100
2003.04.25	1	4.127	100

)

Result: Gas chromatography indicated one major peak (peak No. 1) analyzed on 2003.3.19 and one major peak(peak No. 1) analyzed on 2003.4.25. No new trace impurity peak in the test substance analyzed on 2003.4.25 was detected.

3. Conclusion: The test substance was stable for about 1 month in a dark place at room temperature.

APPENDIX B 1

CONCENTRATION OF 1-BROMOBUTANE IN THE INHALATION CHAMBER OF THE 2-WEEK INHALATION STUDY

CONCENTRATION OF 1-BROMOBUTANE IN THE INHALATION CHAMBER OF THE 2-WEEK INHALATION STUDY

Group Name	Concentration(ppm) Mean ± S.D.	
Control	$0.0\pm~0.0$	
500ppm	500.3 ± 2.5	
1000ppm	1000.5 ± 3.6	
2000ppm	2000.6	
4000ppm	4003.7	
8000ppm	8034.9	

)

APPENDIX B 2

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 2-WEEK INHALATION STUDY OF 1-BROMOBUTANE

Group Name	Temperature (°C) Mean \pm S.D.	Humidity (%) Mean ± S.D.	Ventilation Rate (L/min) Mean ± S.D.	Air Change (time/h) Mean
Control	22.6 ± 0.1	59.1 ± 0.6	104.6 ± 0.3	12.1
$500 \mathrm{ppm}$	22.3 ± 0.1	60.5 ± 0.4	104.2 ± 0.4	12.0
1000ppm	22.2 ± 0.1	60.7 ± 0.5	104.6 ± 1.5	12.1
2000ppm	22.2 ± 0.4	61.1 ± 0.6	104.5 ± 0.8	12.1
4000ppm	22.3	58.6	106.0	12.2
8000ppm	22.5	53.8	106.5	12.3

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ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 2-WEEK INHALATION STUDY OF 1-BROMOBUTANE

APPENDIX C 1

CLINICAL OBSERVATION : SUMMARY, MOUSE : MALE

STUDY NO. : 0481 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

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SEX : MALE

PAGE : 1

linical sign	Group Name	Adminia	stration We	eek-day				 	
-		1-1	1-2	1-4	1-7	2-3	2-7		
COMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0		
	500ppm	0	0	0	0	0	0		
	1000ppm	5	0	1	_	-	-		
	2000ppm	4	-		_	-	-		
	4000ppm	_	-	-		-	-		
	8000ppm	-	-		-	-	-		
BACK POSITION	Control	0	0	0	0	0	0		
	500ppm	0	0	0	0	0	0		
	1000ppm	0	1	1	-	-	-		
	2000ppm	0			~	-	_		
	4000ppm	-	-	-	-	_	-		
	8000ppm	-	-	-	-	-	-		
DERECTION	Control	0	0	0	0	0	0		
	500ppm	0	0	0	0	0	0		
	1000ppm	5	1	1	_	_	_		
	2000ppm	4	_	_	_	-	_		
	4000ppm	_	_	_	_	_	_		
	8000ppm	-	_	-	-	-	-		
LED PERI-GENITALIA	Control	0	0	0	0	0	0		
	500ppm	0	0	0	0	0	0		
	1000ppm	0	Õ	1	_	-			
	2000ppm	Õ	_	_	_	_	_		
	4000ppm	-	_	-	_	-	-		
	4000ppm 8000ppm	-	-	-	-	-	-		
EGULAR BREATHING	Control	0	0	0	0	0	0		
	500ppm	0	Õ	Õ	Õ	Ő	Õ		
	1000ppm	5	Õ	Õ	-	_	_		
	2000ppm	4	_	-	_	_	_		
	4000ppm		_	_	_	_	_		
	8000ppm	-	-	-	-	-	-		
DYPNEA	Control	0	0	0	0	0	0		
	500ppm	Ő	0	Ő	0	Ö	Ő		
	1000ppm	Õ	0	1	-	_	-		
	2000ppm	4	_	-	_	_	_		
	2000ppm 4000ppm	- 4	_	_	_	_	_		
	4000µµm	_	_	_	_	_	-		
	8000ppm	-	-		-	-			

STUDY NO. : 0481 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : MALE

PAGE : 2 Clinical sign Group Name Administration Week-day _ 2-7 1 - 22 - 31 - 11 - 41-7 SUBNORMAL TEMP Control 0 0 0 0 0 0 500ppm 0 0 0 0 0 0 1000ppm 0 0 0 _ -----2000ppm _ --_ 4 _ 4000ppm _ _ _ ~ -----8000ppm ------_ -----

(HAN190)

APPENDIX C 2

CLINICAL OBSERVATION : SUMMARY, MOUSE : FEMALE

STUDY NO. : 0481 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : FEMALE

Administration Week-day Clinical sign Group Name 1 - 21~7 2-3 2-71 - 11 - 40 LOCOMOTOR MOVEMENT DECR Control 0 0 0 0 0 500ppm 0 0 0 0 0 0 1000ppm 0 0 0 0 0 0 2000ppm 5 -_ _ ---4000ppm _ _ _ _ _ ----8000ppm _ _ _ _ 0 0 HUNCHBACK POSITION Control 0 0 0 0 500ppm 0 0 0 0 0 0 1000ppm 0 0 0 0 2 2 2000ppm 0 -_ -----_ 4000ppm ---_ _ _ 8000ppm _ _ _ _ -_ PILOERECTION 0 0 0 0 0 0 Control 500ppm 0 0 0 0 0 0 0 1000ppm 0 0 0 0 1 2000ppm 5 _ _ ----_ _ 4000ppm _ _ _ _ _ _ 8000ppm _ 0 IRREGULAR BREATHING 0 0 0 0 0 Control 500ppm 0 0 0 0 0 0 1000ppm 0 2 0 0 0 0 2000ppm 5 -_ _ _ ----4000ppm _ _ _ _ _ _ -8000ppm -_ BRADYPNEA 0 0 0 0 Control 0 0 500ppm 0 0 0 0 0 0 1000ppm 0 0 0 0 0 0 5 2000ppm ---------4000ppm _ _ _ _ _ 8000ppm _ _ _ _ _ SUBNORMAL TEMP Control 0 0 0 0 0 0 500ppm 0 0 0 0 0 0 1000ppm 0 0 0 0 0 0 2000ppm 5 _ ---_ 4000ppm _ _ _ _ ~ -8000ppm _ _ _ _ _ _

PAGE : 3

APPENDIX D 1

BODY WEIGHT CHANGES : SUMMARY, MOUSE : MALE

STUDY NO. : 0481 ANIMAL : MOUSE Crj:BDF1 UNIT : g REPORT TYPE : A1 2 SEX : MALE			BODY WEIGHT CHANGES ALL ANIMALS	(SUMMARY)			PAGE : 1
Group Name	Administration	week-day					
	0-0	1-2	1-4	1–7	2-3	2-7	
Control	23.1± 1.2	23.5± 1.0	23.8± 1.0	24.4± 1.2	24.8± 1.3	25.3± 1.3	
500ppm	23.1± 1.3	22.6 \pm 1.1	23.2± 0.9	23.5± 1.2	25.0 ± 1.3	24.8± 1.0	
1000ppm !	23.1 ± 1.2	19. 7	17.2	-	_	-	
2000ppm	23.1 ± 1.3	-	-	-	-	-	
4000ppm	23.1± 0.9	-	-	-	-	-	
8000ppm	23.1± 0.8	-		-	-		

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

Test of t

! : Significant test is not applied to this group.

(HAN260)

APPENDIX D 2

BODY WEIGHT CHANGES : SUMMARY, MOUSE : FEMALE

STUDY NO. : 0481 ANIMAL : MOUSE Crj:BDF1 UNIT : g REPORT TYPE : A1 2 SEX : FEMALE			BODY WEIGHT CHANGES ALL ANIMALS	(SUMMARY)			PAGE : 2
Group Name	Administration 0-0	week-day 1-2	1-4	1-7	2-3	2-7	
Control	19.2± 0.8	19.2± 0.8	19.4± 0.3	19.6± 0.8	20.7± 0.8	20.8± 0.6	
500ppm	19.1± 0.9	18.5± 1.3	19.3± 0.8	19.3± 1.2	20.4± 0.9	19.6± 1.0	
1000ppm	19.1± 0.9	18.2± 0.3	19.0 \pm 0.5	19.1± 0.3	18.6± 1.4*	17.5± 1.3**	
2000ppm	19.2± 0.8	-	-	-	-	-	
4000ppm	19.2± 0.9	_	_	-	-		
8000ppm	19.2± 0.8	_	_	_	-		

Test of Dunnett

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** : P ≦ 0.01

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(HAN260)

Significant difference ; $*: P \leq 0.05$

APPENDIX E 1

FOOD CONSUMPTION CHANGES : SUMMARY, MOUSE : MALE

STUDY NO. : 0481 ANIMAL : MOUSE Crj:BDF1 UNIT : g REPORT TYPE : A1 2 SEX : MALE			FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS PAGE :	: 1
Group Name	Administration 1-7(6)	week-day(effective) 2-7(7)	/e)	
Control	4.4± 0.4	4.2± 0.4		
500ppm	4.1± 0.3	4.5± 0.2		
1000ppm	-			
2000ppm	-	-		
4000ppm	-	-		
8000pm	-	-		

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

Test of t

(HAN260)

APPENDIX E 2

FOOD CONSUMPTION CHANGES : SUMMARY, MOUSE : FEMALE

STUDY NO. : 0481 ANIMAL : MOUSE Crj:BDF1 JNIT : g REPORT TYPE : A1 2			CONSUMPTION CHAN	GES (SUMMARY)		
SEX : FEMALE Group Name	Administration 1-7(6)	week-day(effective) 2-7(7)				PAGE :
Control	3.5± 0.3	3.7± 0.3				
500ppm	3.7± 0.2	3.9± 0.1				
1000ppm	3.7± 0.2	3.3± 0.5			·	
2000ppm	-	-				
4000ppm	-	-				
8000ppm	-					
Significant difference ;	*:P≦0.05 *	* : P ≦ 0.01		Test of Dunnett		
(HAN260)	••••••••••••••••••••••••••••••••••••••					BAIS

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APPENDIX F 1

HEMATOLOGY : SUMMARY, MOUSE : MALE

: MALE	REPORT	TYPE : A1													PAGE :
up Name	NO. of Animals	RED BLC 1 O ⁶ /µ	DOD CELL 12	HEMOGLO g⁄dl	BIN	HEMATOC %	RIT	MCV f L		MCH Þg		MCHC g ⁄dl		PLATELE 1 0³/µ	
Control	5	11.08±	0.34	16.4±	0.5	51.1±	2. 0	46.1±	0.9	1 4. 8±	0.2	32.1±	0.3	$1242\pm$	56
500ppm	4	10.40±	0.21**	15.3±	0.3**	48.2±	0.8*	46.4±	0.2	14.8±	0.2	31.8±	0.2	1262土	59
1000ppm	0			_		_		-		-				_	
2000ppm	0	-		-		_		-		_		-		-	
4000ppm	0	-		-		_		—		-		-		-	
8000ppm	0	-		-		_		-		_		_		-	

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(HCL070)

DY NO. : 0481 MAL : MOUS SURE. TIME : : MALE	E Crj:BDF1 1	TYPE : A1				HEMATOLOGY ALL ANIMAI										PAGE	:
up Name	NO. of Animals	₩BC 1 0³/		Dif N-BAND	ferential	WBC (%) N-SEG	l	EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	5	1.50±	0.71	0±	1	16±	7	2±	1	0土	0	1±	1	80土	5	0±	C
500ppm	4	2.74±	1.03	1±	1	7±	1*	2土	1	0土	0	1±	1	89±	1*	0±	(
1000ppm	0	-		-				-		-		-		-			
2000ppm	0	-		-		-		~		-		-		-		-	
4000ppm	0	-		-		_		-		-		-				-	
8000ppm	0	-		_		-		-		-		-		-		-	

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(HCL070)

APPENDIX F 2

HEMATOLOGY : SUMMARY, MOUSE : FEMALE

Crj:BDF1														
	TYPE : A1													PAGE : 3
NO. of Animals			HEMOGLO g ⁄dl	BIN	HEMATOC %	ЖIТ	MCV f £		MCH Pg		MCHC g∕dℓ		PLATELE 1 0³⁄µ	
5	11 . 14±	0.19	16.5±	0.2	51.0±	0.8	45.8±	0.2	14.8±	0.1	32.4±	0.3	1115±	50
5	10.46±	0.23**	15.7±	0.4*	48.4±	0.9**	46.3±	0.7	15.0±	0.1*	32.5±	0.4	1112±	98
5	10. 4 9±	0.29**	15.5±	0.5**	47.4±	1.4**	45.2±	0.7	14.7±	0.1	32.6±	0.6	$1218\pm$	69
0	-		-		_		-		-		-		_	
0	_		-		_		-		_		-		-	
0	-		-		_				-		-		_	
	REPORT NO. of Animals 5 5 5 5 0 0 0	REPORT TYPE : A1 NO. of Animals RED BLOO 1 0 ⁶ /µµ 5 11.14± 5 10.46± 5 10.49± 0 - 0 - 0 -	REPORT TYPE : A1 NO. of Animals RED BLOOD CELL 1 0 ⁵ /µl 5 11.14± 0.19 5 10.46± 0.23** 5 10.49± 0.29** 0 - - 0 - -	REPORT TYPE : A1 NO. of Animals RED BLOOD CELL $1 O^5 / \mu \ell$ HEMOGLO $g / d\ell$ 5 11.14± 0.19 16.5± 5 10.46± 0.23** 15.7± 5 10.49± 0.29** 15.5± 0 - - 0 - -	Cr j: BDF1 Al REPORT TYPE : A1 I NO. of Animals RED BLOOD CELL $g \neq d2$ 5 11.14± 5 11.14± 0 - 0 - 0 - 0 - 0 - 0 - 0 - 0 - 0 - 0 - 0 - 0 - 0 - 0 - 0 - 0 -	Cr j: BDF1 ALL ANIMALS (REPORT TYPE : A1 NO. of RED BLOOD CELL μ HEMOGLOBIN $g / d2$ HEMATOG $\%$ 5 11.14± 0.19 16.5± 0.2 51.0± 5 10.46± 0.23** 15.7± 0.4* 48.4± 5 10.49± 0.29** 15.5± 0.5** 47.4± 0 - - - - - 0 - - - - -	REPORT TYPE : A1 NO. of Animals RED BLOOD CELL $1 O^{6} / \mu \ell$ HEMOGLOBIN $g / d\ell$ HEMATOCRIT % 5 11.14± 0.19 16.5± 0.2 51.0± 0.8 5 10.46± 0.23** 15.7± 0.4* 48.4± 0.9** 5 10.49± 0.29** 15.5± 0.5** 47.4± 1.4** 0 - - - - - 0 - - - -	ALL ANIMALS (3W) REPORT TYPE : A1 NO. of Animals RED BLOOD CELL $1 O^6 / \mu^2$ HEMOGLOBIN g / d^2 HEMATOCRIT % MCV f 2 5 11.14± 0.19 16.5± 0.2 51.0± 0.8 45.8± 5 10.46± 0.23** 15.7± 0.4* 48.4± 0.9** 46.3± 5 10.49± 0.29** 15.5± 0.5** 47.4± 1.4** 45.2± 0 - - - - - - 0 - - - - - -	ALL ANIMALS (3W) REPORT TYPE : A1 NO. of Animals RED BLOOD CELL 1 $0^6 / \mu^2$ HEMOGLOBIN g / d^2 HEMATOCRIT % MCV f 2 5 11.14± 0.19 16.5± 0.2 51.0± 0.8 45.8± 0.2 5 10.46± 0.23** 15.7± 0.4* 48.4± 0.9** 46.3± 0.7 5 10.49± 0.29** 15.5± 0.5** 47.4± 1.4** 45.2± 0.7 0 - - - - - - - 0 - - - - - - -	ALL ANIMALS (3W) REPORT TYPE : A1 NO. of Animals RED BLOOD CELL 1 0 ⁶ /µ ² HEMOGLOBIN g / d ² HEMATOCRIT % MCV f 2 MCH p g 5 11. 14± 0. 19 16. 5± 0. 2 51. 0± 0.8 45. 8± 0.2 14. 8± 5 10. 46± 0. 23** 15. 7± 0. 4* 48. 4± 0. 9** 46. 3± 0.7 15. 0± 5 10. 49± 0. 29** 15. 5± 0. 5** 47. 4± 1. 4** 45. 2± 0.7 14. 7± 0 - - - - - - - 0 - - - - - - -	ALL ANIMALS (3W) ALL ANIMALS (3W) REPORT TYPE : A1 NO. of Animals RED BLOOD CELL $1 C^{p}/\mu^{2}$ HEMOGLOBIN g/d^{2} HEMATOCRIT % MCV f 2 MCH p g 5 11.14± 0.19 16.5± 0.2 51.0± 0.8 45.8± 0.2 14.8± 0.1 5 10.46± 0.23** 15.7± 0.4* 48.4± 0.9** 46.3± 0.7 15.0± 0.1* 5 10.49± 0.29** 15.5± 0.5** 47.4± 1.4** 45.2± 0.7 14.7± 0.1 0 - - - - - - - - 0 - - - - - - - -	ALL ANIMALS (3W) REPORT TYPE : A1 NO. of Animals RED BLOOD CELL 1 C^{ϕ}/μ^{2} HEMOGLOBIN g / d2 HEMATOCRIT % MCV f 2 MCH p g MCH g / d2 MCH g / d2 5 11.14± 0.19 16.5± 0.2 51.0± 0.8 45.8± 0.2 14.8± 0.1 32.4± 5 10.46± 0.23** 15.7± 0.4* 48.4± 0.9** 46.3± 0.7 15.0± 0.1* 32.5± 5 10.49± 0.29** 15.5± 0.5** 47.4± 1.4** 45.2± 0.7 14.7± 0.1 32.6± 0 - - - - - - - - 0 - - - - - - - - 0 - - - - - - - - - 0 - - - - - - - - - -	ALL ANIMALS (3W) REPORT TYPE : A1 NO. of Animals RED BLOOD CELL 10 ⁶ /µl HEMOCLOBIN g / dl HEMATOCRIT % MCV f MCH p MCHC g / dl MCHC g / dl 5 11.14± 0.19 16.5± 0.2 51.0± 0.8 45.8± 0.2 14.8± 0.1 32.4± 0.3 5 10.46± 0.23** 15.7± 0.4* 48.4± 0.9** 46.3± 0.7 15.0± 0.1* 32.5± 0.4 5 10.49± 0.29** 15.5± 0.5** 47.4± 1.4** 45.2± 0.7 14.7± 0.1 32.6± 0.6 0 - - - - - - - - - 0 - - - - - - - - 0 - - - - - - - - 0 - - - - - - - - -	ALL ANIMALS (3W) REPORT TYPE : A1 NO. of Animals RED BLOOD CELL $1 O^{0} / \mu^{2}$ HEMOCLOBIN g / d^{2} HEMATOCRIT % MCV f 2 MCH p g MCHC g / d^{2} PIATELE f 2 5 11.14± 0.19 16.5± 0.2 51.0± 0.8 45.8± 0.2 14.8± 0.1 32.4± 0.3 1115± 5 10.46± 0.23** 15.7± 0.4* 48.4± 0.9** 46.3± 0.7 15.0± 0.1* 32.5± 0.4 1112± 5 10.49± 0.29** 15.5± 0.5** 47.4± 1.4** 45.2± 0.7 14.7± 0.1 32.6± 0.6 1218± 0 - - - - - - - - 0 - - - - - - - - - 0 - - - - - - - - - 0 - - - - - - - - <td< td=""></td<>

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up Name	NO. of Animals	₩BC 1 0³⁄µ	l	Dif N-BAND	ferential	WBC (% N-SEG)	EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	5	1.84±	0. 79	1±	1	11±	4	1±	1	0±	0	1±	1	87±	4	0±	
500ppm	5	1.33±	0.23	0±	1	13±	5	3±	2	0±	0	1±	1	83±	6	0±	
1000ppm	5	0.78±	0.45*	0±	0	15±	4	3±	3	0土	0	2±	2	80±	4	0±	
2000ppm	0	_		-		-				-		-		-		-	
4000ppm	0			-		-		-		-		-		-		-	
8000ppm	0	-				_		_		_		_		-		-	

HEMATOLOGY (SUMMARY)

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(HCL070)

STUDY NO. : 0481

# APPENDIX G 1

BIOCHEMISTRY : SUMMARY, MOUSE : MALE

| TUDY NO, : 0481<br>NIMAL : MOUSE<br>EASURE. TIME : 1 | Crj:BDF1          |                       |                  | BIOCHEMISTRY (SUMMARY)<br>ALL ANIMALS ( 3W) |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                  |                        |                       |  |  |  |  |  |  |
|------------------------------------------------------|-------------------|-----------------------|------------------|---------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|------------------------|-----------------------|--|--|--|--|--|--|
| EASURE. TIME - 1<br>EX : MALE                        |                   | YPE : A1              |                  |                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                  |                        | PAGE : 1              |  |  |  |  |  |  |
| roup Name                                            | NO. of<br>Animals | TOTAL PROTEIN<br>g∕d£ | ALBUMIN<br>g ⁄dl | A/G RATIO                                   | T-BILIRUBIN<br>mg∕d£                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | GLUCOSE<br>mg/dl | T-CHOLESTEROL<br>mg/dl | TRIGLYCERIDE<br>mg⁄dl |  |  |  |  |  |  |
| Control                                              | 5                 | 5.2± 0.3              | 3.0± 0.0         | 1.4± 0.1                                    | 0.16± 0.04                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 224± 27          | 75± 10                 | 32± 16                |  |  |  |  |  |  |
| 500ppm                                               | 5                 | 4.9± 0.1*             | 2.9± 0.2         | 1.4± 0.2                                    | 0.16± 0.02                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 252± 21          | 100± 15*               | 24± 7                 |  |  |  |  |  |  |
| 1000ppm                                              | 0                 | -                     |                  | -                                           | _                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | _                | -                      | -                     |  |  |  |  |  |  |
| 2000ppm                                              | 0                 | -                     | -                | _                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | _                | -                      | -                     |  |  |  |  |  |  |
| 4000ppm                                              | 0                 | -                     | -                | -                                           | -                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | -                | -                      | -                     |  |  |  |  |  |  |
| 8000ppm                                              | 0                 | -                     | -                |                                             | and the second se | -                | _                      | -                     |  |  |  |  |  |  |

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| SURE. TIME : 1<br>: MALE | REPORT TYPE : A1  |                       |    |         |   |             |   |          |     |          |      |               |   |             | PAGE : |
|--------------------------|-------------------|-----------------------|----|---------|---|-------------|---|----------|-----|----------|------|---------------|---|-------------|--------|
| roup Name<br>Control     | NO. of<br>Animals | PHOSPHOLIPID<br>mg/dl |    |         |   | GPT<br>IU/L |   |          |     |          |      | G-GTP<br>IU∕£ |   | CPK<br>IU/2 |        |
|                          | 5                 | $165\pm$              | 21 | $42\pm$ | 6 | $20\pm$     | 6 | $265\pm$ | 146 | 280±     | 16   | 1土            | 1 | 161±        | 127    |
| 500ppm                   | 5                 | 177±                  | 20 | 37±     | 4 | 20±         | 6 | 178±     | 63  | $249\pm$ | 12** | 2±            | 1 | 56土         | 21     |
| 1000ppm                  | 0                 | -                     |    | _       |   | -           |   | -        |     |          |      | -             |   | -           |        |
| 2000ppm                  | 0                 | `_                    |    | _       |   | -           |   | ••       |     | _        |      | _             |   | -           |        |
| 4000ppm                  | 0                 | _                     |    | _       |   | -           |   | -        |     | -        |      | _             |   | -           |        |
| 8000ppm                  | 0                 | -                     |    | -       |   | -           |   | -        |     | -        |      | -             |   | -           |        |

(HCL074)

| SURE. TIME : 1<br>: MALE | 1<br>REPORT TYPE : A1 |                  |       |                 |   |                   |     |                   |    |                  |     |                  |                | PAGE : |  |
|--------------------------|-----------------------|------------------|-------|-----------------|---|-------------------|-----|-------------------|----|------------------|-----|------------------|----------------|--------|--|
| up Name                  | NO. of<br>Animals     | UREA NI<br>mg⁄dl |       | SODIUM<br>mEq⁄£ |   | POTASSI<br>m Eq / |     | CHLORIDE<br>mEq∕£ |    | CALCIU∦<br>mg∕dℓ |     | INORGAN<br>mg/dl | IIC PHOSPHORUS |        |  |
| Control                  | 5                     | 28.3±            | 3.8   | 149±            | 1 | 5.1±              | 0.6 | 118±              | 2  | 8.7±             | 0.1 | 5.9±             | 1.2            |        |  |
| 500ppm                   | 5                     | 14.7±            | 1.4** | 148±            | 1 | 4.9±              | 0.4 | 121±              | 2* | 8.7±             | 0.2 | 7.1±             | 1.0            |        |  |
| 1000ppm                  | 0                     | -                |       | -               |   | -                 |     |                   |    | -                |     | -                |                |        |  |
| 2000ppm                  | 0                     | _                |       |                 |   | -                 |     | -                 |    | -                |     | -                |                |        |  |
| 4000ppm                  | 0                     | ~                |       | -               |   | -                 |     | -                 |    | -                |     | -                |                |        |  |
| 8000ppm                  | 0                     | _                |       | -               |   | _                 |     | -                 |    | _                |     | -                |                |        |  |

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#### APPENDIX G 2

BIOCHEMISTRY : SUMMARY, MOUSE : FEMALE

(2-WEEK STUDY)

| EASURE. TIME : 1<br>EX : FEMALE |                   | TYPE : A1            |      |              |         |     |                  |      |                  |    |                  |        |                   | PAGE : |
|---------------------------------|-------------------|----------------------|------|--------------|---------|-----|------------------|------|------------------|----|------------------|--------|-------------------|--------|
| coup Name                       | NO. of<br>Animals | TOTAL PROTE<br>g /dl |      | BUMIN<br>⁄dl | A/G RAT | 010 | T−BILII<br>mg∕d£ |      | GLUCOSE<br>mg⁄dl |    | T−CHOLE<br>mg∕dℓ | STEROL | TRIGLYCI<br>mg∕dl | BRIDE  |
| Control                         | 5                 | 5.3± 0.              | 2 3. | 5土 0.2       | 2.0±    | 0.3 | 0.15±            | 0.03 | 172±             | 28 | 75±              | 9      | 19±               | 7      |
| 500ppm                          | 5                 | 5.1± 0.              | 1 3. | 3± 0.0       | 1.8±    | 0.1 | 0.15±            | 0.02 | 223±             | 16 | 92±              | 10     | 21±               | 7      |
| 1000ppm                         | 5                 | 5.4± 0.              | 2 3. | 6± 0.2       | 2.0±    | 0.3 | 0.18±            | 0.02 | 188±             | 67 | 109±             | 23**   | 17土               | 12     |
| 2000ppm                         | 0                 | -                    |      | -            | -       |     | -                |      | -                |    | -                |        | -                 |        |
| 4000ppm                         | 0                 | -                    |      | -            | -       |     | -                |      | _                |    | -                |        |                   |        |
| 8000ppm                         | 0                 | _                    |      | _            | -       |     | _                |      | _                |    | -                |        | -                 |        |

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| : FEMALE | REPORT 1          | YPE : A1         |       |             |                                       |             |   |              |    |             |      |               |   |             | PAGE : |
|----------|-------------------|------------------|-------|-------------|---------------------------------------|-------------|---|--------------|----|-------------|------|---------------|---|-------------|--------|
| up Name  | NO. of<br>Animals | PHOSPHO<br>mg/dl | LIPID | GOT<br>IU/S | · · · · · · · · · · · · · · · · · · · | GPT<br>IU∕₽ |   | LDH<br>IU⁄\$ | 2  | ALP<br>IU/1 | !    | G-GTP<br>IU∕£ |   | CPK<br>IU/A |        |
| Control  | 5                 | $153\pm$         | 10    | 49±         | 7                                     | 22±         | 5 | $259\pm$     | 82 | 413±        | 46   | 1±            | 1 | $123\pm$    | 72     |
| 500ppm   | 5                 | $154\pm$         | 14    | 41±         | 3                                     | $21\pm$     | 4 | 190±         | 71 | 328±        | 12** | 1土            | 1 | $65\pm$     | 52     |
| 1000ppm  | 5                 | 160±             | 43    | 56±         | 11                                    | $24\pm$     | 6 | $253\pm$     | 60 | 340土        | 46*  | 1±            | 1 | 53±         | 32     |
| 2000ppm  | 0                 | -                |       | -           |                                       |             |   |              |    | -           |      | _             |   | -           |        |
| 4000ppm  | 0                 | ~                |       | -           |                                       | -           |   | -            |    | -           |      | -             |   | -           |        |
| 8000ppm  | 0                 | -                |       |             |                                       |             |   | -            |    | -           |      | -             |   | -           |        |

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| K : FEMALE | REPORT            | TYPE : A1        |        |                         |   |                  |     |                   |    |                  |     |                  |                | PAGE : |
|------------|-------------------|------------------|--------|-------------------------|---|------------------|-----|-------------------|----|------------------|-----|------------------|----------------|--------|
| pup Name   | NO. of<br>Animals | UREA NI<br>mg⁄dl | TROGEN | SODIUM<br>mEq∕ <b>£</b> |   | POTASSI<br>mEq⁄. |     | CHLORIDH<br>mEq⁄£ |    | CALCIU)<br>mg⁄dl |     | INORGAN<br>mg⁄dl | NIC PHOSPHORUS |        |
| Control    | 5                 | 24.7±            | 2.8    | 150±                    | 2 | 4.6±             | 0.3 | 119±              | 1, | 8.7±             | 0.2 | 6.3±             | 1.6            |        |
| 500ppm     | 5                 | 13.4±            | 3. 0** | $147\pm$                | 1 | 4.4±             | 0.4 | $118\pm$          | 1  | 8.4±             | 0.4 | 6.4±             | 1.3            |        |
| 1000ppm    | Б                 | 14.3±            | 7.1**  | 147±                    | 3 | 4.1±             | 0.3 | 119±              | 4  | 8.6±             | 0.3 | 6.5±             | 1.0            |        |
| 2000ppm    | 0                 | -                |        | -                       |   | -                |     | . –               |    | -                |     | -                |                |        |
| 4000ppm    | 0                 | _                |        | -                       |   | _                |     | -                 |    |                  |     | -                |                |        |
| 8000ppm    | 0                 | _                |        | -                       |   | -                |     |                   |    | _                |     | _                |                |        |

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(HCL074)

### APPENDIX H 1

GROSS FINDINGS : SUMMARY, MOUSE : MALE : DEAD AND MORIBUND ANIMALS (2-WEEK STUDY)

| ANIMAL<br>REPORT TYPE | : 0481<br>: MOUSE Crj:BDF1<br>: A1<br>: MALE | JSE Crj:BDF1     DEAD AND MORIBUND ANIMALS (0- 3W) |                  |                 |                  |                  |  |  |  |
|-----------------------|----------------------------------------------|----------------------------------------------------|------------------|-----------------|------------------|------------------|--|--|--|
| Organ                 | Findings                                     | Group Name<br>NO. of Animals                       | Control<br>0 (%) | 500ppm<br>0 (%) | 1000ppm<br>5 (%) | 2000ppm<br>5 (%) |  |  |  |
| lung                  | red                                          |                                                    | - ( -)           | - ( -)          | 0 ( 0)           | 1 (20)           |  |  |  |
|                       | red zone                                     |                                                    | - ( -)           | - ( -)          | 1 (20)           | 3 (60)           |  |  |  |
| liver                 | white zone                                   |                                                    | - ( -)           | - ( -)          | 1 (20)           | 0 ( 0)           |  |  |  |
|                       | red zone                                     |                                                    | - ( -)           | - ( -)          | 1 (20)           | 0 ( 0)           |  |  |  |
|                       | accentuation of lobular structure            |                                                    | - ( -)           | - ( -)          | 2 (40)           | 0 ( 0)           |  |  |  |

(HPT080)

| REPORT TYPE | : 0481<br>: MOUSE Crj:BDF1<br>: A1<br>: MALE | GROSS FINDINGS (SUMMARY)<br>DEAD AND MORIBUND ANIMALS (O· | GROSS FINDINGS (SUMMARY)<br>DEAD AND MORIBUND ANIMALS (O- 3W) |                  |  |  |  |
|-------------|----------------------------------------------|-----------------------------------------------------------|---------------------------------------------------------------|------------------|--|--|--|
| Organ       | Findings                                     | Group Name<br>NO. of Animals                              | 4000ppm<br>5 (%)                                              | 8000ppm<br>5 (%) |  |  |  |
| lung        | red                                          |                                                           | 0 ( 0)                                                        | 0 ( 0)           |  |  |  |
|             | red zone                                     |                                                           | 2 (40)                                                        | 3 (60)           |  |  |  |
| liver       | white zone                                   |                                                           | 0 ( 0)                                                        | 0 ( 0)           |  |  |  |
|             | red zone                                     |                                                           | 0 ( 0)                                                        | 0 ( 0)           |  |  |  |
|             | accontuation of lobular structure            |                                                           | 0 ( 0)                                                        | 0 ( 0)           |  |  |  |
|             |                                              |                                                           |                                                               |                  |  |  |  |

(HPT080)

### APPENDIX H 2

GROSS FINDINGS : SUMMARY, MOUSE : MALE : SACRIFICED ANIMALS (2-WEEK STUDY)

| ANIMAL :<br>REPORT TYPE : | 0481<br>MOUSE Crj:BDF1<br>A1<br>MALE | GROSS FINDINGS (SUMMARY)<br>SACRIFICED ANIMALS ( 3\) |                   |                  | PAGE : 1         |
|---------------------------|--------------------------------------|------------------------------------------------------|-------------------|------------------|------------------|
| Organ                     | Findings                             | Group Name Contro<br>NO. of Animals 5 (%)            | 1 500ppm<br>5 (%) | 1000ppm<br>0 (%) | 2000ppm<br>0 (%) |
| spleen                    | black zone                           | 0 ( 0)                                               | 1 (20)            | - ( -)           | ( -)             |
| forestomach               | thick                                | 0 ( 0)                                               | 1 (20)            | - ( -)           | - ( -)           |
| liver                     | white zone                           | 0 ( 0)                                               | 1 (20)            | - ( -)           | - ( -)           |
|                           |                                      |                                                      |                   |                  |                  |

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| ANIMAL :<br>REPORT TYPE : | 0481<br>MOUSE Crj:BDF1<br>A1<br>MALE | GROSS FINDINGS (SUMMARY)<br>SACRIFICED ANIMALS ( 3\) |                  |                  | PAGE : 2 |
|---------------------------|--------------------------------------|------------------------------------------------------|------------------|------------------|----------|
| 0rgan                     | Findings                             | Group Name<br>NO. of Animals                         | 4000ppm<br>0 (%) | 8000ррт<br>0 (%) |          |
| spleen                    | black zone                           |                                                      | - ( -)           | - ( -)           |          |
| forestomach               | thick                                |                                                      | - ( -)           | - ( -)           |          |
| liver                     | white zone                           |                                                      | - ( -)           | - ( -)           |          |
|                           |                                      |                                                      |                  |                  |          |

(HPT080)

### APPENDIX H 3

GROSS FINDINGS : SUMMARY, MOUSE : FEMALE : DEAD AND MORIBUND ANIMALS (2-WEEK STUDY)

| ANIMAL :<br>REPORT TYPE : | 0481<br>MOUSE Crj:BDF1<br>A1<br>FEMALE | GROSS FINDINGS (SUMMARY)<br>DEAD AND MORIBUND ANIMALS | (O- 3W)          |                 |                  | PAGE : 3         |
|---------------------------|----------------------------------------|-------------------------------------------------------|------------------|-----------------|------------------|------------------|
| Organ                     | Findings                               | Group Name<br>NO. of Animals                          | Control<br>0 (%) | 500ppm<br>0 (%) | 1000ppm<br>0 (%) | 2000ppm<br>5 (%) |
| lung                      | red                                    |                                                       | - ( -)           | - ( -)          | - ( -)           | 1 (20)           |
|                           | red zone                               |                                                       | - ( -)           | - ( -)          | - ( -)           | 3 (60)           |
| spleen                    | black zone                             |                                                       | - ( -)           | - ( -)          | - ( -)           | 1 (20)           |
| liver                     | accentuation of lobular structure      |                                                       | - ( -)           | - ( -)          | - ( -)           | 5 (100)          |
| thoracic ca               | pleural fluid                          |                                                       | - ( -)           | - ( -)          | ( -)             | 3 (60)           |
|                           |                                        |                                                       |                  |                 |                  |                  |

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(HPT080)

| ANIMAL :<br>REPORT TYPE : | 0481<br>MOUSE Crj:BDF1<br>A1<br>FEMALE | GROSS FINDINGS (SUMMARY)<br>DEAD AND MORIBUND ANIMALS (O- 3W) |                       |  |  |  |  |
|---------------------------|----------------------------------------|---------------------------------------------------------------|-----------------------|--|--|--|--|
| Organ                     | Findings                               | Group Name 400<br>NO. of Animals 5 (%)                        | 0ppm 8000ppm<br>5 (%) |  |  |  |  |
| lung                      | red                                    | 0 ( 0)                                                        | 0 ( 0)                |  |  |  |  |
|                           | red zone                               | 0 ( 0)                                                        | 3 (60)                |  |  |  |  |
| spleen                    | black zone                             | 0 ( 0)                                                        | 0 ( 0)                |  |  |  |  |
| liver                     | accentuation of lobular structure      | 0 ( 0)                                                        | 0 ( 0)                |  |  |  |  |
| thoracic ca               | ploural fluid                          | 0 ( 0)                                                        | 0 ( 0)                |  |  |  |  |
|                           |                                        |                                                               |                       |  |  |  |  |

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### APPENDIX H 4

GROSS FINDINGS : SUMMARY, MOUSE : FEMALE : SACRIFICED ANIMALS (2-WEEK STUDY)

|             | : 0481 GROSS FINDINGS (SUMMARY)<br>: MOUSE Crj:BDF1 SACRIFICED ANIMALS ( 3W)<br>: A1 |                              |                  |                 |                  |                  |  |  |  |
|-------------|--------------------------------------------------------------------------------------|------------------------------|------------------|-----------------|------------------|------------------|--|--|--|
|             | AI<br>FEMALE                                                                         |                              |                  |                 |                  | PAGE : 3         |  |  |  |
| Organ       | Findings                                                                             | Group Name<br>NO. of Animals | Control<br>5 (%) | 500ppm<br>5 (%) | 1000ppm<br>5 (%) | 2000ppm<br>0 (%) |  |  |  |
| thymus      | atrophic                                                                             |                              | 0 ( 0)           | 0 ( 0)          | 1 (20)           | - ( -)           |  |  |  |
| spleen      | black zone                                                                           |                              | 1 (20)           | 0 ( 0)          | 0 ( 0)           | - ( -)           |  |  |  |
| forestomach | thick                                                                                |                              | 0 ( 0)           | 1 (20)          | 1 (20)           | - ( -)           |  |  |  |
| ovary       | cyst                                                                                 |                              | 1 (20)           | 0 ( 0)          | 0 ( 0)           | - ( -)           |  |  |  |
|             |                                                                                      |                              |                  |                 |                  |                  |  |  |  |

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(HPT080)

| ANIMAL :<br>REPORT TYPE : | 0481<br>MOUSE Crj:BDF1<br>A1<br>FEMALE | GROSS FINDINGS (SUMMARY)<br>SACRIFICED ANIMALS ( 3W) |                  |                  | PAGE : 4 |
|---------------------------|----------------------------------------|------------------------------------------------------|------------------|------------------|----------|
| Organ                     | Findings                               | Group Name<br>NO. of Animals                         | 4000ppm<br>0 (%) | 8000ppm<br>0 (%) |          |
| thymus                    | atrophic                               |                                                      | - ( -)           | ( -)             |          |
| spleen                    | black zone                             |                                                      | - ( -)           | - ( -)           |          |
| forestomach               | thick                                  |                                                      | - ( -)           | - ( -)           |          |
| ovary                     | cyst                                   |                                                      | - ( -)           | - ( -)           |          |
|                           |                                        |                                                      |                  |                  |          |
| (HPT080)                  |                                        |                                                      |                  |                  | BAIS 4   |

### APPENDIX I 1

# ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOUSE : MALE

(2-WEEK STUDY)

| STUDY NO. : 0481<br>ANIMAL : MOUSE Crj:BDF1<br>REPORT TYPE : A1<br>SEX : MALE<br>JNIT: g |                   |              | ORGAN WEIGHT:ABSOLUTE (SUMMARY)<br>SURVIVAL ANIMALS ( 3W) |              |              |              |              |          |  |  |
|------------------------------------------------------------------------------------------|-------------------|--------------|-----------------------------------------------------------|--------------|--------------|--------------|--------------|----------|--|--|
| Group Name                                                                               | NO. of<br>Animals | Body Weight  | THYMUS                                                    | ADRENALS     | TESTES       | HEART        | LUNGS        | PAGE : 1 |  |  |
| Control                                                                                  | 5                 | 21.4± 0.9    | 0.049± 0.006                                              | 0.011± 0.002 | 0.186± 0.021 | 0.126± 0.024 | 0.141± 0.017 |          |  |  |
| 500ppm                                                                                   | . 5               | 21.6± 1.0    | 0.028± 0.005**                                            | 0.010± 0.003 | 0.177± 0.020 | 0.123± 0.013 | 0.150± 0.010 |          |  |  |
| 1000ppm                                                                                  | 0                 | · _          | -                                                         | -            |              | -            | -            |          |  |  |
| 2000ppm                                                                                  | 0                 | -            | -                                                         | -            | -            |              | -            |          |  |  |
| 4000ppm                                                                                  | 0                 | -            | -                                                         | -            | -            | -            | -            |          |  |  |
| 8000ppm                                                                                  | 0                 | -            | -                                                         | -            | -            | -            | -            |          |  |  |
| Significant                                                                              | difference ;      | *:P≦ 0.05 ** | : P ≤ 0.01                                                | Tes          | t of t       |              |              |          |  |  |

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(HCL040)

BAIS 4

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| STUDY NO. : 0481<br>ANIMAL : MOUSE Crj:BDF1<br>REPORT TYPE : A1 |                   |            | ORGAN WEIGHT: ABSOLUTE (SUMMARY)<br>SURVIVAL ANIMALS ( 3W) |       |            |        |             |       |  |                                           |          |
|-----------------------------------------------------------------|-------------------|------------|------------------------------------------------------------|-------|------------|--------|-------------|-------|--|-------------------------------------------|----------|
| SEX : MALE<br>UNIT: g                                           |                   |            |                                                            |       |            |        |             |       |  |                                           | PAGE : 2 |
| Group Name                                                      | NO. of<br>Animals | KIDNEYS    | SPLE                                                       | EN    | LIV        | ER     | BRA         | IN    |  | <br>· · · · · · · · · · · · · · · · · · · |          |
| Control                                                         | 5                 | 0.330± 0.0 | 27 0.037±                                                  | 0.007 | 0.962±     | 0.032  | 0.431±      | 0.035 |  |                                           |          |
| 500ppm                                                          | 5                 | 0.351± 0.0 | 39 0.032±                                                  | 0.004 | $1.077\pm$ | 0.084* | 0.420 $\pm$ | 0.016 |  |                                           |          |
| 1000ppm                                                         | 0                 |            | _                                                          |       |            |        | -           |       |  |                                           |          |
| 2000ppm                                                         | 0                 | _          | _                                                          |       |            |        | _           |       |  |                                           |          |
| 4000ppm                                                         | 0                 | -          | _                                                          |       | -          |        | -           |       |  |                                           |          |
| 8000ppm                                                         | 0                 |            | -                                                          |       | -          |        |             |       |  |                                           |          |

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(HCL040)

# PPENDIX I 2

## ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOUSE : FEMALE

(2-WEEK STUDY)

| X : FEMALE<br>IIT: g |                   |          |      |             |         |        |       |             |        |            |       |        |        | PAGE : |
|----------------------|-------------------|----------|------|-------------|---------|--------|-------|-------------|--------|------------|-------|--------|--------|--------|
| oup Name             | NO. of<br>Animals | Body We  | ight | THYM        | JS      | ADRE   | NALS  | OVAR        | IES    | HEAR       | [     | LUNG   | 5      |        |
| Control              | 5                 | 17.2± 0. | 8    | 0.061 $\pm$ | 0.006   | 0.009± | 0.002 | 0.022 $\pm$ | 0.005  | 0.102±     | 0.013 | 0.124± | 0.005  |        |
| 500ppm               | 5                 | 16.9± 1. | 0    | 0.032±      | 0.002** | 0.010± | 0.001 | 0.016±      | 0.004  | 0.096±     | 0.005 | 0.136± | 0.012  |        |
| 1000ppm              | 5                 | 15.3± 1. | 1*   | 0.022±      | 0.009** | 0.011± | 0.002 | 0.014±      | 0.002* | $0.097\pm$ | 0.015 | 0.137± | 0.005* |        |
| 2000ppm              | 0                 | -        |      | -           |         | -      |       | -           |        | -          |       | -      |        |        |
| 4000ppm              | 0                 | -        |      | _           |         | -      |       | -           |        | -          |       | -      |        |        |
| 8000ppm              | 0                 | -        |      | _           |         | -      |       | -           |        | -          |       | _      |        |        |

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(HCL040)

| STUDY NO. : 0481<br>ANIMAL : MOUSE Crj:BDF1<br>REPORT TYPE : A1<br>SEX : FEMALE |                   |             | ORGAN WEIGHT:ABSOLUTE (SUMMARY)<br>SURVIVAL ANIMALS ( 3W) |             |         |            |       |               |       |  |  |  |  |         |
|---------------------------------------------------------------------------------|-------------------|-------------|-----------------------------------------------------------|-------------|---------|------------|-------|---------------|-------|--|--|--|--|---------|
| UNIT: g                                                                         |                   |             |                                                           |             |         |            |       |               |       |  |  |  |  | PAGE: 4 |
| Group Name                                                                      | NO. of<br>Animals | KID         | NEYS                                                      | SPLI        | EEN     | LIV        | ER    | BRA           | IN .  |  |  |  |  |         |
| Control                                                                         | 5                 | 0.231±      | 0.009                                                     | 0.036±      | 0.005   | 0.753±     | 0.047 | 0.428±        | 0.013 |  |  |  |  |         |
| 500ppm                                                                          | 5                 | 0.248 $\pm$ | 0.016                                                     | 0.029 $\pm$ | 0.002   | 0.814±     | 0.045 | 0.422 $\pm$   | 0.010 |  |  |  |  |         |
| 1000ppm                                                                         | 5                 | 0.236±      | 0.010                                                     | 0.026 $\pm$ | 0.006** | $0.806\pm$ | 0.060 | 0.414 $\pm$   | 0.008 |  |  |  |  |         |
| 2000ppm                                                                         | 0                 | -           |                                                           | -           |         | -          |       | -             |       |  |  |  |  |         |
| 4000ppm                                                                         | 0                 | _           |                                                           | _           |         | _          |       | -             |       |  |  |  |  |         |
| 8000ppm                                                                         | 0                 | -           |                                                           | -           |         | -          |       | -             |       |  |  |  |  |         |
| Significant                                                                     | difference ;      | * : P ≦ 0.  | 05 **                                                     | : P ≦ 0.01  |         |            | T     | est of Dunnet | t     |  |  |  |  |         |

(HCL040)

### APPENDIX J 1

# ORGAN WEIGHT, RELATIVE : SUMMARY, MOUSE : MALE

(2-WEEK STUDY)

| STUDY NO. : 0481<br>ANIMAL : MOUS<br>REPORT TYPE : A1<br>SEX : MALE | E Crj:BDF1        | ORGAN WEIGHT:RELATIVE (SUMMARY)<br>SURVIVAL ANIMALS ( 3W) |                |              |              |              |              |          |  |  |  |
|---------------------------------------------------------------------|-------------------|-----------------------------------------------------------|----------------|--------------|--------------|--------------|--------------|----------|--|--|--|
| UNIT: %                                                             |                   |                                                           |                |              |              |              |              | PAGE : 1 |  |  |  |
| Group Name                                                          | NO. of<br>Animals | Body Weight<br>(g)                                        | THYMUS         | ADRENALS     | TESTES       | HEART        | LUNGS        |          |  |  |  |
| Control                                                             | 5                 | 21.4± 0.9                                                 | 0.227± 0.027   | 0.050± 0.008 | 0.866± 0.077 | 0.585± 0.099 | 0.655± 0.068 |          |  |  |  |
| 500ppm                                                              | 5                 | 21.6± 1.0                                                 | 0.130± 0.023** | 0.045± 0.013 | 0.820± 0.084 | 0.566± 0.047 | 0.694± 0.019 |          |  |  |  |
| 1000ppm                                                             | 0                 | -                                                         | -              | -            | -            | -            | -            |          |  |  |  |
| 2000ppm                                                             | 0                 | -                                                         | ~              | -            | -            | -            | -            |          |  |  |  |
| 4000ppm                                                             | 0                 | -                                                         | · _ ·          | -            | -            | -            | -            |          |  |  |  |
| 8000pm                                                              | 0                 | -                                                         | -              | -            | -            | -            | -            |          |  |  |  |
| Significant                                                         | difference ;      | * : P ≤ 0.05 **                                           | : P ≤ 0.01     | Te:          | st of t      |              |              |          |  |  |  |

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BAIS 4

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| TUDY NO. : 0481<br>NIMAL : MOUSE Crj:BDF1<br>EPORT TYPE : A1<br>EX : MALE<br>NIT: % |                   |              | ORGAN<br>SURVIN |                |              |              |
|-------------------------------------------------------------------------------------|-------------------|--------------|-----------------|----------------|--------------|--------------|
| JNIT: %<br>Group Name                                                               | NO. of<br>Animals | KIDNEYS      | SPLEEN          | LIVER          | BRAIN        | <br>PAGE : 2 |
| Control                                                                             | 5                 | 1.538± 0.105 | 0.170± 0.025    | 4.490± 0.215   | 2.009± 0.110 |              |
| 500ppm                                                                              | 5                 | 1.619± 0.133 | 0.147± 0.012    | 4.974± 0.224** | 1.944± 0.080 |              |
| 1000ppm                                                                             | 0                 | -            | -               |                | -            |              |
| 2000ppm                                                                             | 0                 | -            | -               | -              | -            |              |
| 4000ppm                                                                             | 0                 | -            | -               | -              | _            |              |
| 8000pm                                                                              | 0                 | -            | -               |                | -            |              |
| Significant                                                                         | difference ;      | *:P≦0.05 **: | P ≦ 0.01        | Test           | of t         |              |

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(HCL042)

### APPENDIX J 2

### ORGAN WEIGHT, RELATIVE : SUMMARY, MOUSE : FEMALE

(2-WEEK STUDY)

| STUDY NO. : 0481<br>ANIMAL : MOUS<br>REPORT TYPE : A1<br>SEX : FEMALE | E Crj:BDF1        |                    | ORGAN WEIGHT:RELATIVE (SUMMARY)<br>SURVIVAL ANIMALS ( 3W) |                  |               |                   |                |          |  |  |  |  |
|-----------------------------------------------------------------------|-------------------|--------------------|-----------------------------------------------------------|------------------|---------------|-------------------|----------------|----------|--|--|--|--|
| UNIT: %                                                               |                   |                    |                                                           |                  |               |                   |                | PAGE : 3 |  |  |  |  |
| Group Name                                                            | NO. of<br>Animals | Body Weight<br>(g) | THYMUS                                                    | ADRENALS         | OVARIES       | HEART             | LUNGS          |          |  |  |  |  |
| Control                                                               | 5                 | 17.2± 0.8          | 0.356± 0.043                                              | $0.050\pm 0.011$ | 0.129± 0.027  | 0.594± 0.050      | 0.719± 0.025   |          |  |  |  |  |
| 500ppm                                                                | 5                 | 16.9± 1.0          | 0.192± 0.018**                                            | 0.057± 0.007     | 0.095± 0.025  | 0.570± 0.037      | 0.802± 0.037   |          |  |  |  |  |
| 1000ppm                                                               | 5                 | 15.3± 1.1*         | 0.141± 0.054**                                            | 0.071± 0.011*    | 0.092± 0.008* | $0.629 \pm 0.054$ | 0.899± 0.085** |          |  |  |  |  |
| 2000ppm                                                               | 0                 | -                  | -                                                         | -                | -             |                   | -              |          |  |  |  |  |
| 4000ppm                                                               | 0                 | -                  |                                                           | -                | -             | -                 | _              |          |  |  |  |  |
| 8000ppm                                                               | 0                 | -                  | -                                                         | -                | -             | -                 | -              |          |  |  |  |  |
| Significant                                                           | difference ;      | *:P≤0.05 **        | : P ≤ 0.01                                                | Tes              | t of Dunnett  |                   |                |          |  |  |  |  |
| (HCL042)                                                              |                   |                    |                                                           |                  |               |                   |                | BAIS 4   |  |  |  |  |

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| Crj:BDF1          |                                                 |                                                                                                                                                     | )                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                |
|-------------------|-------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                   |                                                 |                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | PAGE : 4                                                                                                                                                                                                                                                                                                                                                                                                       |
| NO. of<br>Animals | KIDNEYS                                         | SPLEEN                                                                                                                                              | LIVER                                                                                                                                                                                                                                                                                                                                  | BRAIN                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                |
| 5                 | 1.346± 0.012                                    | 0.208± 0.020                                                                                                                                        | 4.380± 0.171                                                                                                                                                                                                                                                                                                                           | 2.495± 0.170                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                |
| 5                 | 1.470± 0.096*                                   | 0.172± 0.007*                                                                                                                                       | 4.825± 0.104*                                                                                                                                                                                                                                                                                                                          | 2.504± 0.105                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                |
| 5                 | 1.546± 0.105**                                  | 0.166± 0.027*                                                                                                                                       | 5.267± 0.310**                                                                                                                                                                                                                                                                                                                         | 2.710± 0.161                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                |
| 0                 | -                                               | -                                                                                                                                                   | -                                                                                                                                                                                                                                                                                                                                      | _                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                |
| 0                 | -                                               | -                                                                                                                                                   | -                                                                                                                                                                                                                                                                                                                                      | _                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                |
| 0                 | -                                               |                                                                                                                                                     | -                                                                                                                                                                                                                                                                                                                                      | -                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                |
|                   | NO. of<br>Animals<br>5<br>5<br>5<br>5<br>0<br>0 | NO. of<br>Animals     KIDNEYS       5     1.346±     0.012       5     1.470±     0.096*       5     1.546±     0.105**       0     -       0     - | Cr j: BDF1       SURVIV.         N0. of       KIDNEYS       SPLEEN         Animals       5       1. $346 \pm 0.012$ 0. $208 \pm 0.020$ 5       1. $346 \pm 0.012$ 0. $208 \pm 0.020$ 5       1. $470 \pm 0.096 *$ 0. $172 \pm 0.007 *$ 5       1. $546 \pm 0.105 * *$ 0. $166 \pm 0.027 *$ 0       -       -         0       -       - | Crj:BDF1       SURVIVAL ANIMALS ( 3W)         NO. of<br>Animals       KIDNEYS       SPLEEN       LIVER         5       1.346 $\pm$ 0.012       0.208 $\pm$ 0.020       4.380 $\pm$ 0.171         5       1.346 $\pm$ 0.012       0.208 $\pm$ 0.020       4.380 $\pm$ 0.171         5       1.470 $\pm$ 0.096*       0.172 $\pm$ 0.007*       4.825 $\pm$ 0.104*         5       1.546 $\pm$ 0.105**       0.166 $\pm$ 0.027*       5.267 $\pm$ 0.310**         0       -       -       -         0       -       -       -         0       -       -       - | NO. of<br>Animals       KIDNEYS       SPLEEN       LIVER       BRAIN         5 $1.346 \pm 0.012$ $0.208 \pm 0.020$ $4.380 \pm 0.171$ $2.495 \pm 0.170$ 5 $1.470 \pm 0.096 *$ $0.172 \pm 0.007 *$ $4.825 \pm 0.104 *$ $2.504 \pm 0.105$ 5 $1.546 \pm 0.105 * *$ $0.166 \pm 0.027 *$ $5.267 \pm 0.310 * *$ $2.710 \pm 0.161$ 0       -       -       -       -       -         0       -       -       -       - |

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(HCL042)

### APPENDIX K 1

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY, MOUSE : MALE : DEAD AND MORIBUND ANIMALS (2-WEEK STUDY)

#### STUDY NO. : 0481 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 SEX : MALE

#### HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) DEAD AND MORIBUND ANIMALS (0- 3W)

| Organ         | Findings                      | Group Name         Control           No. of Animals on Study         0           Grade         1         2         3         4           (%)         (%)         (%)         (%) | 500ppm<br>0<br><u>1 2 3 4</u><br>(%) (%) (%) (%) | 1000ppm<br>5<br><u>1 2 3 4</u><br>(%) (%) (%) (%) | 2000ppm<br>5<br><u>1 2 3 4</u><br>(%) (%) (%) (%) |
|---------------|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|---------------------------------------------------|---------------------------------------------------|
| {Respiratory  | system)                       |                                                                                                                                                                                  |                                                  |                                                   |                                                   |
| nasal cavit   | necrosis:olfactory epithelium | < 0><br>( -) ( -) ( -) ( -)                                                                                                                                                      | < 0><br>( -) ( -) ( -) ( -)                      | < 5><br>3 2 0 0<br>( 60) ( 40) ( 0) ( 0)          | < 5><br>0 2 0 0<br>( 0) ( 40) ( 0) ( 0)           |
| lung          | congestion                    | < 0><br><br>( -) ( -) ( -) ( -)                                                                                                                                                  | < 0><br><br>( -) ( -) ( -) ( -)                  | < 5><br>1 0 0 0<br>( 20) ( 0) ( 0) ( 0)           | < 5><br>0 4 1 0<br>( 0) ( 80) ( 20) ( 0)          |
|               | hemorrhage                    | <br>( -) ( -) ( -) ( -)                                                                                                                                                          | <br>( -) ( -) ( -) ( -)                          | 0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                    | 0 1 0 0<br>( 0) ( 20) ( 0) ( 0)                   |
|               | edema                         | ( -) ( -) ( -) ( -)                                                                                                                                                              | <br>( -) ( -) ( -) ( -)                          | 0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                    | 0 1 0 0<br>( 0) ( 20) ( 0) ( 0)                   |
|               | edema:perivascular            | ( -) ( -) ( -) ( -)                                                                                                                                                              | ( -) ( -) ( -) ( -)                              | 3 2 0 0<br>(60)(40)(0)(0)                         | 4 1 0 0<br>(80) (20) (0) (0)                      |
| {Hematopoieti | c system)                     |                                                                                                                                                                                  |                                                  |                                                   |                                                   |
| thymus        | atrophy                       | < 0>                                                                                                                                                                             | < 0>                                             | < 5><br>0 0 1 0                                   | < 5><br>0 0 0 0                                   |

-(-) (-) (-) (-) (-) (-) (0) (0) (20) (0)

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

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

b b : Number of animals with lesion

(c) c:b/a \* 100

(HPT150)

BAIS4

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

| STUDY NO.   | : | 0481           |
|-------------|---|----------------|
| ANIMAL      | : | MOUSE Crj:BDF1 |
| REPORT TYPE | : | A1             |
| SEX         | : | MALE           |

#### HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) DEAD AND MORIBUND ANIMALS (0- 3W)

 $\overline{\phantom{a}}$ 

0- 3W)

| Organ                        | Findings                                                                                                                 | Group Name         4000ppm           No. of Animals on Study         5           Grade         1         2         3         4           (%)         (%)         (%)         (%) | 8000ppm<br>5<br><u>1 2 3 4</u><br>(%) (%) (%) (%) |      |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|------|
| {Respiratory                 | system)                                                                                                                  |                                                                                                                                                                                  |                                                   |      |
| nasal cavit                  | necrosis:olfactory epithelium                                                                                            | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                                                                                                                           | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)            |      |
| lung                         | congestion                                                                                                               | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                                                                                                                           | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)            |      |
|                              | hemorrhage                                                                                                               | 0 2 0 0<br>( 0) ( 40) ( 0) ( 0)                                                                                                                                                  | 3 0 0 0<br>(60)(0)(0)(0)                          |      |
|                              | edema                                                                                                                    | 0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                                                                                                                                   | 0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                    |      |
|                              | edema:perivascular                                                                                                       | 4 0 0 0<br>(80) (0) (0) (0)                                                                                                                                                      | 0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                    |      |
| {Hematopoieti                | c system}                                                                                                                |                                                                                                                                                                                  |                                                   |      |
| thymus                       | atrophy                                                                                                                  | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                                                                                                                           | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)            |      |
| Grade<br>< a ><br>b<br>( c ) | 1 : Slight 2 : Moderate<br>a : Number of animals examined at the<br>b : Number of animals with lesion<br>c : b / a * 100 | 3 : Marked 4 : Severe<br>9 site                                                                                                                                                  |                                                   | <br> |

(HPT150)

BAIS4

#### STUDY NO. : 0481 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 SEX : MALE

#### HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) DEAD AND

| ND | MORIBUND | ANIMALS | (0- | 3W) | - |  |
|----|----------|---------|-----|-----|---|--|
|    |          |         |     |     |   |  |

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| Organ               | Findings                                                                                      | Group Name         Control           No. of Animals on Study         0           Grade         1         2         3         4           (%)         (%)         (%)         (%) | 500ppm<br>0<br><u>1 2 3 4</u><br>(%) (%) (%) (%) | 1000ppm<br>5<br><u>1 2 3 4</u><br>(%) (%) (%) (%)          | 2000ppm<br>5<br><u>1 2 3 4</u><br>(%) (%) (%) (%) |
|---------------------|-----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|------------------------------------------------------------|---------------------------------------------------|
| {Hematopoie:        | tic system}                                                                                   |                                                                                                                                                                                  |                                                  |                                                            |                                                   |
| spleen              | atrophy                                                                                       | < 0><br>                                                                                                                                                                         | < 0><br><br>( -) ( -) ( -) ( -)                  | $\langle 5 \rangle$<br>1 0 0 0<br>(20) (0) (0) (0)         | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)            |
| {Circulator         | y system)                                                                                     |                                                                                                                                                                                  |                                                  |                                                            |                                                   |
| heart               | hemorrhage                                                                                    | < 0><br><br>( -) ( -) ( -) ( -)                                                                                                                                                  | < 0><br><br>( -) ( -) ( -) ( -)                  | <pre> &lt; 5&gt;<br/>0 0 0 0<br/>( 0) ( 0) ( 0) ( 0)</pre> | < 5><br>3 0 0 0<br>( 60) ( 0) ( 0) ( 0)           |
|                     | ground glass appearance                                                                       | <br>( -) ( -) ( -) ( -)                                                                                                                                                          | ( -) ( -) ( -) ( -)                              | 0 4 0 0<br>( 0) ( 80) ( 0) ( 0)                            | 0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                    |
| {Digestive :        | system}                                                                                       |                                                                                                                                                                                  |                                                  |                                                            |                                                   |
| liver               | necrosis:central                                                                              | < 0><br><br>( -) ( -) ( -) ( -)                                                                                                                                                  | < 0><br><br>( -) ( -) ( -) ( -)                  | < 5><br>0 0 1 0<br>( 0) ( 0) ( 20) ( 0)                    | < 5><br>5 0 0 0<br>(100) ( 0) ( 0) ( 0)           |
|                     | vacuolic change                                                                               | <br>( -) ( -) ( -) ( -)                                                                                                                                                          | <br>( -) ( -) ( -) ( -)                          | 5 0 0 0<br>(100) ( 0) ( 0) ( 0)                            | 4 1 0 0<br>(80) (20) (0) (0)                      |
| Grade<br>< a ><br>b | 1: Slight 2: Moderate<br>a: Number of animals examined at<br>b: Number of animals with lesion |                                                                                                                                                                                  |                                                  |                                                            |                                                   |

c:b/a\*100 (c)

(HPT150)

STUDY NO. : 0481 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) DEAD AND MORIBUND ANIMALS (0- 3W)

8000ppm

No. of Animals on Study 5 5 3 4 Grade 1 2 3 4 2 1 (%) (%) (%) (%) (%) (%) (%) (%) Findings\_\_\_\_ {Hematopoietic system} < 5> < 5> 0 0 0 0 0 0 0 0 atrophy 

#### {Circulatory system}

Organ\_\_\_\_

spleen

| heart |                         | < 5>                      | < 5>                      |
|-------|-------------------------|---------------------------|---------------------------|
|       | hemorrhage              | 3 2 0 0<br>(60)(40)(0)(0) | 0 0 0 0<br>( 0) ( 0) ( 0) |
|       |                         |                           |                           |
|       | ground glass appearance | 0 0 0                     | 0 0 0 0                   |
|       |                         | ( 0) ( 0) ( 0) ( 0)       | ( 0) ( 0) ( 0) ( 0)       |

Group Name

#### {Digestive system}

| liver |                  |            | < 5> |         |   |         |   | < 5>    |   |          |   |          |   |         |   |         |
|-------|------------------|------------|------|---------|---|---------|---|---------|---|----------|---|----------|---|---------|---|---------|
|       | necrosis:central | 0          | ,    | 0       | , | 0       | , | 0       | , | 0        | , | 0        | , | 0       |   | 0       |
|       |                  | ( 0)       | ί    | 0)      | ( | 0)      | ţ | 0)      | ( | 0)       | ( | 0)       | ( | 0)      | ( | 0)      |
|       | vacuolic change  | 5<br>(100) | (    | 0<br>0) | ( | 0<br>0) | ( | 0<br>0) | ( | 1<br>20) | ( | 4<br>80) | ( | 0<br>0) |   | 0<br>0) |

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

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

b b : Number of animals with lesion

(c) c:b/a\*100

(HPT150)

BAIS4

PAGE: 4

4000ppm

STUDY NO. : 0481 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 SEX : MALE

#### HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) DEAD AND MORIBUND ANIMALS (0- 3W)

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| Organ                        |                                                                                                                                     | Dup Name         Control           of Animals on Study         0           ade         1         2         3         4           (%)         (%)         (%)         (%)         (%) | 500ppm<br>0<br><u>1 2 3 4</u><br>(%) (%) (%) (%) | 1000ppm<br>5<br><u>1 2 3 4</u><br>(%) (%) (%) (%) | 2000ppm<br>5<br><u>1 2 3 4</u><br>(%) (%) (%) (%) |
|------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|---------------------------------------------------|---------------------------------------------------|
| {Digestive                   | system}                                                                                                                             |                                                                                                                                                                                      |                                                  |                                                   |                                                   |
| liver                        | hydropic change                                                                                                                     | < 0><br><br>( -) ( -) ( -) ( -)                                                                                                                                                      | < 0><br><br>( -) ( -) ( -) ( -)                  | < 5><br>1 0 0 0<br>(20) (0) (0) (0)               | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)            |
|                              | hemorrhage:central                                                                                                                  | <br>( -) ( -) ( -) ( -)                                                                                                                                                              | ( -) ( -) ( -) ( -)                              | 0 0 5 0<br>( 0) ( 0) (100) ( 0)                   | 0 0 0 0 0 .<br>( 0) ( 0) ( 0) ( 0)                |
|                              | hemorrhage:portal                                                                                                                   | ( -) ( -) ( -) ( -)                                                                                                                                                                  | ( -) ( -) ( -) ( -)                              | 0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                    | 0 1 0 0<br>( 0) ( 20) ( 0) ( 0)                   |
| {Urinary sy                  | ystem}                                                                                                                              |                                                                                                                                                                                      |                                                  |                                                   |                                                   |
| kidney                       | tubular necrosis:proximale tubule                                                                                                   | < 0><br><br>( -) ( -) ( -) ( -)                                                                                                                                                      | < 0><br><br>( -) ( -) ( -) ( -)                  | < 5><br>0 0 1 0<br>( 0) ( 0) ( 20) ( 0)           | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)            |
| {Reproducti                  | ive system}                                                                                                                         |                                                                                                                                                                                      |                                                  |                                                   |                                                   |
| testis                       | germ cell necrosis                                                                                                                  | < 0><br>( -) ( -) ( -) ( -)                                                                                                                                                          | < 0><br><br>( -) ( -) ( -) ( -)                  | < 5><br>0 1 0 0<br>( 0) ( 20) ( 0) ( 0)           | < 5><br>1 0 0 0<br>( 20) ( 0) ( 0) ( 0)           |
| Grade<br>< a ><br>b<br>( c ) | 1 : Slight 2 : Moderate 3 : M<br>a : Number of animals examined at the site<br>b : Number of animals with lesion<br>c : b / a * 100 | Marked 4 : Severe                                                                                                                                                                    |                                                  |                                                   |                                                   |

(HPT150)

BAIS4

STUDY NO. : 0481 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 SEX : MALE

#### HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) DEAD AND MORIBUND ANIMALS (0- 3W)

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| Organ                        |                                                                                                                               | up Name 4000ppm<br>of Animals on Study 5<br>de <u>1 2 3 4</u><br>(%) (%) (%) (%) | $ \begin{array}{c} 8000 \text{ppm} \\ 5 \\ \underline{1 \ 2 \ 3 \ 4} \\ (\%) \ (\%) \ (\%) \ (\%) \end{array} $ |          |
|------------------------------|-------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|----------|
| {Digestive                   | system)                                                                                                                       |                                                                                  |                                                                                                                 |          |
| liver                        | hydropic change                                                                                                               | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                           | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                                                          |          |
|                              | hemorrhage:central                                                                                                            | 0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                                   | 0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                                                                  |          |
|                              | hemorrhage:portal                                                                                                             | 0 2 3 0<br>( 0) ( 40) ( 60) ( 0)                                                 | 0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                                                                  |          |
| {Urinary sy                  | rstem}                                                                                                                        |                                                                                  |                                                                                                                 | ·        |
| kidney                       | tubular necrosis:proximale tubule                                                                                             | <pre>&lt; 5&gt; 0 0 0 0 ( 0) ( 0) ( 0) ( 0)</pre>                                | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                                                          |          |
| {Reproducti                  | ve system)                                                                                                                    |                                                                                  |                                                                                                                 |          |
| testis                       | germ cell necrosis                                                                                                            | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                           | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                                                          |          |
| Grade<br>< a ><br>b<br>( c ) | 1: Slight 2: Moderate 3: M<br>a: Number of animals examined at the site<br>b: Number of animals with lesion<br>c: b / a * 100 | arked 4 : Severe                                                                 |                                                                                                                 | <u>.</u> |

(HPT150)

#### APPENDIX K 2

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY, MOUSE : MALE : SACRIFICED ANIMALS (2-WEEK STUDY)

|             |                              | Group Name Control                                                                                                                          | 500ppm                                                      | 1000ppm                                              | 2000ppm                                                    |
|-------------|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|------------------------------------------------------|------------------------------------------------------------|
| rgan        | Findings                     | No. of Animals on Study         5           Grade         1         2         3         4           (%)         (%)         (%)         (%) | $ \begin{array}{cccccccccccccccccccccccccccccccccccc$       | $\begin{array}{cccccccccccccccccccccccccccccccccccc$ | 0<br><u>1</u> <u>2</u> <u>3</u> <u>4</u><br>(%) (%) (%) (% |
| Respiratory | system)                      |                                                                                                                                             |                                                             |                                                      |                                                            |
| asal cavit  | atrophy:olfactory epithelium | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                                                                                      | < 5><br>5 0 0 0<br>(100) ( 0) ( 0) ( 0)                     | < 0><br><br>( -) ( -) ( -) ( -)                      | < 0><br><br>( -) ( -) ( -) ( -                             |
| ung         | basophilic change:bronchiole | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                                                                                      | < 5><br>5 0 0 0<br>(100) ( 0) ( 0) ( 0)                     | < 0><br>                                             | < 0><br>                                                   |
| Hematopoiet | ic system)                   |                                                                                                                                             |                                                             |                                                      |                                                            |
| hymus       | atrophy                      | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                                                                                      | < 5><br>2 0 0 0<br>(40) (0) (0) (0)                         | < 0><br><br>( -) ( -) ( -) ( -)                      | < 0><br>                                                   |
| pleen       | deposit of melanin           | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                                                                                      | < 5><br>1 0 0 0<br>( 20) ( 0) ( 0) ( 0)                     | < 0><br>                                             | < 0><br>                                                   |
| Digestive s | ystem)                       |                                                                                                                                             |                                                             |                                                      |                                                            |
| tomach      | erosion:forestomach          | <pre>&lt; 5&gt; 0 0 0 0 ( 0) ( 0) ( 0) ( 0)</pre>                                                                                           | <pre> &lt; 5&gt;     1 0 0 0     ( 20) ( 0) ( 0) ( 0)</pre> | < 0><br><br>( -) ( -) ( -) ( -)                      | < 0><br><br>( -) ( -) ( -) ( -                             |

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)

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(c) c:b/a\*100

(HPT150)

STUDY NO. : 0481

BAIS4

STUDY NO. : 0481 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 SEX : MALE

### HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) SACRIFICED ANIMALS ( 3W)

| Organ                        |                                                                                                                         | Group Name         4000ppm           No. of Animals on Study         0           Grade         1         2         3         4 | 8000ppm<br>0<br><u>1 2 3 4</u><br>(%) (%) (%) (%) |      |
|------------------------------|-------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|------|
| {Respiratory                 | system}                                                                                                                 |                                                                                                                                |                                                   |      |
| nasal cavit                  | atrophy:olfactory epithelium                                                                                            | < 0><br><br>( -) ( -) ( -) ( -)                                                                                                | < 0><br><br>( -) ( -) ( -) ( -)                   |      |
| lung                         | basophilic change:bronchiole                                                                                            | < 0><br><br>( -) ( -) ( -) ( -)                                                                                                | < 0><br><br>( -) ( -) ( -) ( -)                   |      |
| {Hematopoieti                | ic system}                                                                                                              |                                                                                                                                |                                                   |      |
| thymus                       | atrophy                                                                                                                 |                                                                                                                                | < 0><br>( -) ( -) ( -) ( -)                       |      |
| spleen                       | deposit of melanin                                                                                                      |                                                                                                                                | < 0><br>( -) ( -) ( -) ( -)                       |      |
| {Digestive sy                | ystem)                                                                                                                  |                                                                                                                                |                                                   |      |
| stomach                      | erosion:forestomach                                                                                                     | < 0><br><br>( -) ( -) ( -) ( -)                                                                                                | < 0><br>( -) ( -) ( -) ( -)                       |      |
| Grade<br>< a ><br>b<br>( c ) | 1: Slight 2: Moderate 3<br>a: Number of animals examined at the s<br>b: Number of animals with lesion<br>c: b / a * 100 | : Marked 4 : Severe<br>te                                                                                                      |                                                   | <br> |

### (HPT150)

BAIS4

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| Organ                        | Findings                                                                                                                 | Group Name<br>No. of Animals on Study<br>Grade <u>1</u> (%) | Control<br>5<br>2 3 4<br>(%) (%) (%) | 500ppm<br>5<br><u>1 2 3 4</u><br>(%) (%) (%) (%) | $ \begin{array}{c} 1000 \text{pm} \\ 0 \\ \underline{1  2  3  4} \\ (\%)  (\%)  (\%)  (\%) \end{array} $ | 2000ppm<br>0<br><u>1 2 3 4</u><br>(%) (%) (%) (%) |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|--------------------------------------|--------------------------------------------------|----------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| Digestive                    | system)                                                                                                                  |                                                             | ·                                    |                                                  |                                                                                                          | · · · · · · · · · · · · · · · · · · ·             |
| stomach                      | hyperplasia:forestomach                                                                                                  | 0<br>( 0)                                                   | < 5><br>0 0 0<br>( 0) ( 0) ( 0)      | < 5><br>0 2 0 0<br>( 0) ( 40) ( 0) ( 0)          | < 0><br>                                                                                                 | < 0><br><br>( -) ( -) ( -) ( -)                   |
| iver                         | necrosis:focal                                                                                                           | 0<br>( 0)                                                   | < 5><br>0 0 0<br>( 0) ( 0) ( 0)      | < 5><br>0 1 0 0<br>( 0) ( 20) ( 0) ( 0)          | < 0><br><br>( -) ( -) ( -) ( -)                                                                          | < 0><br><br>( -) ( -) ( -) ( -)                   |
| Grade<br>( a ><br>b<br>( c ) | 1 : Slight 2 : Moderate<br>a : Number of animals examined at the<br>b : Number of animals with lesion<br>c : b / a * 100 | 3: Marked 4: Severe<br>site                                 | e                                    |                                                  |                                                                                                          |                                                   |

STUDY NO.:0481ANIMAL:MOUSE Crj:BDF1REPORT TYPE:A1SEX:MALE

### HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) SACRIFICED ANIMALS ( 3W)

| Organ                        | Findings                                                                                                           | Group Name         4000ppm           No. of Animals on Study         0           Grade         1         2         3         4           (%)         (%)         (%)         (%) | $ \begin{array}{cccccccccccccccccccccccccccccccccccc$ |                                       |
|------------------------------|--------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|---------------------------------------|
|                              |                                                                                                                    |                                                                                                                                                                                  |                                                       | · · · · · · · · · · · · · · · · · · · |
| {Digestive                   | system)                                                                                                            |                                                                                                                                                                                  |                                                       |                                       |
| stomach                      |                                                                                                                    | < 0>                                                                                                                                                                             | < 0>                                                  |                                       |
|                              | hyperplasia:forestomach                                                                                            | ( -) ( -) ( -) ( -)                                                                                                                                                              | ( -) ( -) ( -) ( -)                                   |                                       |
| liver                        | necrosis:focal                                                                                                     | < 0>                                                                                                                                                                             | < 0>                                                  |                                       |
|                              | necrosis-rocar                                                                                                     | ( -) ( -) ( -) ( -)                                                                                                                                                              | ( -) ( -) ( -) ( -)                                   |                                       |
| Grade<br>< a ><br>b<br>( c ) | 1: Slight 2: Moderate<br>a: Number of animals examined at th<br>b: Number of animals with lesion<br>c: b / a * 100 | 3 : Marked 4 : Severe<br>e site                                                                                                                                                  |                                                       |                                       |
|                              |                                                                                                                    |                                                                                                                                                                                  |                                                       |                                       |

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(HPT150)

BAIS4

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### APPENDIX K 3

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY, MOUSE : FEMALE : DEAD AND MORIBUND ANIMALS (2-WEEK STUDY)

| REPORT TYPE : | A1<br>FEMALB                  |                                                                |                               |                |                                                  |                                                   |
|---------------|-------------------------------|----------------------------------------------------------------|-------------------------------|----------------|--------------------------------------------------|---------------------------------------------------|
| Organ         | Findings                      | Group Name<br>No. of Animals on Study<br>Grade <u>1</u><br>(%) | Contr-<br>0<br>2 3<br>(%) (%) | 01<br>4<br>(%) | 500ppm<br>0<br><u>1 2 3 4</u><br>(%) (%) (%) (%) | 1000ppm<br>0<br><u>1 2 3 4</u><br>(%) (%) (%) (%) |
| {Respiratory  | system)                       |                                                                |                               |                |                                                  |                                                   |
| nasal cavit   | necrosis:olfactory epithelium | -<br>( -)                                                      | < 0><br><br>( _) ( _)         | -<br>( -)      | < 0><br>                                         | < 0><br>                                          |
| lung          | congestion                    | -<br>( -)                                                      | < 0><br><br>( _) ( _)         |                | < 0><br><br>( -) ( -) ( -) ( -)                  | < 0><br><br>( -) ( -) ( -) ( -)                   |
|               | hemorrhage                    | -<br>( -)                                                      | <br>( -) ( -)                 | -<br>( -)      | ( -) ( -) ( -)                                   | ( -) ( -) ( -) ( -)                               |
|               | edema:perivascular            | - ( -)                                                         | <br>( -) ( -)                 | -<br>( -)      |                                                  | <br>( _) ( _) ( _) ( _)                           |

#### HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) DEAD AND MORIBUND ANIMALS (0- 3W)

ANIMAL : MOUSE Crj:BDF1

STUDY NO. : 0481

{Hematopoietic system} spleen < 0> < 0> < 0> < 5> deposit of melanin \_ \_ \_ ~ - -- - -1 0 0 0 (--) (--) (--) ( -) ( -) ( -) ( -) ( -) ( -) ( -) ( -) (20) (0) (0) (0) {Circulatory system} heart < 0> < 0>  $\langle 0 \rangle$ < 5> hemorrhage - -~ - -\_ \_ \_ \_ 2 0 0 0 ( -) ( -) ( -) ( -) ( -) ( -) ( -) ( --) ( -) ( -) ( -) ( -) (40) (0) (0) (0) 1 : Slight Grade 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 PAGE : 7

2000ppm 5

(%) (%) (%)

< 5> 4 0 0 0 (80) (0) (0) (0)

< 5> 1 1 0 0 (20) (20) (0) (0)

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

1 0 0

(80) (20) (0) (0)

2

3 4

.

(%)

4

<sup>(</sup>HPT150)

#### STUDY NO. : 0481 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 SEX : FEMALE

### HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) DEAD AND MORIBUND ANIMALS (0- 3W)

DEAD AND MORIBUND ANIMALS (0- 3W)

| Organ         | Findings                      | Group Name         4000ppm           No. of Animals on Study         5           Grade         1         2         3         4           (%)         (%)         (%)         (%)         (%) | $ \begin{array}{cccccccccccccccccccccccccccccccccccc$ |  |
|---------------|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|--|
| {Respiratory  | system)                       |                                                                                                                                                                                              |                                                       |  |
| nasal cavit   | necrosis:olfactory epithelium | <pre></pre>                                                                                                                                                                                  | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                |  |
| lung          | congestion                    | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                                                                                                                                       | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                |  |
|               | hemorrhage                    | 1 0 0 0<br>(20) (0) (0) (0)                                                                                                                                                                  | 3 0 0 0<br>(60) (0) (0) (0)                           |  |
|               | edema:perivascular            | $\begin{array}{cccccccccccccccccccccccccccccccccccc$                                                                                                                                         | 0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                        |  |
| {Hematopoieti | c system)                     |                                                                                                                                                                                              |                                                       |  |
| spleen        | deposit of melanin            | <pre> &lt; 5&gt;<br/>0 0 0 0<br/>( 0) ( 0) ( 0) ( 0)</pre>                                                                                                                                   | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                |  |
| {Circulatory  | system)                       |                                                                                                                                                                                              |                                                       |  |
| heart         | hemorrhage                    | < 5><br>1 0 0 0                                                                                                                                                                              | < 5><br>0 0 0 0                                       |  |

(20) (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

PAGE : 8

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#### STUDY NO. : 0481 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 SEX : FEMALE

### HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) DEAD AND MORIBUND ANIMALS (0~ 3W)

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| Organ                        | No                                                                                                                                        | coup Name         Control           o. of Animals on Study         0           rade         1         2         3         4            (%)         (%)         (%)         (%) | 500ppm<br>0<br><u>1 2 3 4</u><br>(%) (%) (%) (%) | 1000ppm<br>0<br><u>1 2 3 4</u><br>(%) (%) (%) (%) | 2000ppm<br>5<br><u>1 2 3 4</u><br>(%) (%) (%) (%) |
|------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|---------------------------------------------------|---------------------------------------------------|
| {Circulator                  | ry system}                                                                                                                                |                                                                                                                                                                                |                                                  |                                                   |                                                   |
| heart                        | ground glass appearance                                                                                                                   | < 0><br><br>( -) ( -) ( -) ( -)                                                                                                                                                | < 0><br><br>( -) ( -) ( -) ( -)                  | < 0><br><br>( -) ( -) ( -) ( -)                   | < 5><br>0 3 2 0<br>( 0) ( 60) ( 40) ( 0)          |
| {Digestive                   | system)                                                                                                                                   |                                                                                                                                                                                |                                                  |                                                   |                                                   |
| liver                        | vacuolic change                                                                                                                           | < 0><br>                                                                                                                                                                       | < 0><br><br>( -) ( -) ( -) ( -)                  | < 0><br><br>( -) ( -) ( -) ( -)                   | < 5><br>4 0 0 0<br>(80) (0) (0) (0)               |
|                              | hemorrhage:central                                                                                                                        | ( -) ( -) ( -) ( -)                                                                                                                                                            |                                                  | ( -) ( -) ( -) ( -)                               | 0 0 5 0<br>( 0) ( 0) (100) ( 0)                   |
|                              | hemorrhage:portal                                                                                                                         | ( -) ( -) ( -) ( -)                                                                                                                                                            |                                                  | ( -) ( -) ( -) ( -)                               | 0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                    |
| Grade<br>< a ><br>b<br>( c ) | <pre>l: Slight 2: Moderate 3:<br/>a: Number of animals examined at the site<br/>b: Number of animals with lesion<br/>c: b / a * 100</pre> | Marked 4 : Severe                                                                                                                                                              |                                                  |                                                   |                                                   |

(HPT150)

BAIS4

STUDY NO. : 0481 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 SEX : FEMALE

### HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) DEAD AND MORIBUND ANIMALS (0- 3W)

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| rgan                    | М                                                                                                                        | Group Name         4000ppm           No. of Animals on Study         5           Grade         1         2         3         4 | $ \begin{array}{cccccccccccccccccccccccccccccccccccc$ |  |
|-------------------------|--------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|--|
| Circulatory             | y system)                                                                                                                |                                                                                                                                |                                                       |  |
| eart                    | ground glass appearance                                                                                                  | < 5><br>0 3 1 0<br>( 0) (60) (20) ( 0)                                                                                         | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                |  |
| Digestive s             | system}                                                                                                                  |                                                                                                                                |                                                       |  |
| ivər                    | vacuolic change                                                                                                          | < 5><br>0 5 0 0<br>( 0) (100) ( 0) ( 0)                                                                                        | < 5><br>0 5 0 0<br>( 0) (100) ( 0) ( 0)               |  |
|                         | hemorrhage:central                                                                                                       | 0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                                                                                 | 0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                        |  |
|                         | hemorrhage:portal                                                                                                        | 0 3 1 0<br>( 0) (60) (20) ( 0)                                                                                                 | 0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                        |  |
| rade<br>a ><br>b<br>c ) | 1: Slight 2: Moderate 3:<br>a: Number of animals examined at the sit<br>b: Number of animals with lesion<br>c: b/a * 100 | Marked 4 : Severe<br>te                                                                                                        |                                                       |  |

### APPENDIX K 4

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY, MOUSE : FEMALE : SACRIFICED ANIMALS (2-WEEK STUDY)

### HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) SACRIFICED ANIMALS ( 3W)

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### STUDY NO. : 0481 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 SEX : FEMALE

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| Organ                        |                                                                                                                               |                                              | $     \frac{4}{(\%)} \frac{1}{(\%)} \frac{2}{(\%)} \frac{3}{(\%)} \frac{4}{(\%)} \frac{1}{(\%)} \frac{2}{(\%)} \frac{3}{(\%)} \frac{4}{(\%)} \frac{1}{(\%)} \frac{2}{(\%)} \frac{1}{(\%)} \frac{2}{(\%)} \frac{1}{(\%)} \frac{1}{(\%)}$ | 1000ppm<br>5<br><u>1 2 3 4</u><br>(%) (%) (%) (%) | 2000ppm<br>0<br><u>1 2 3 4</u><br>(%) (%) (%) (%) |
|------------------------------|-------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|---------------------------------------------------|
| {Respiratory                 | system)                                                                                                                       |                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                   |                                                   |
| nasal cavit                  | atrophy:olfactory epithelium                                                                                                  | < 5><br>0 0 0<br>( 0) ( 0) ( 0) (            | <pre> &lt; 5&gt; 0 5 0 0 0 0) (100) ( 0) ( 0) ( 0) ( 0)</pre>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | < 5><br>5 0 0 0<br>(100) ( 0) ( 0) ( 0)           | < 0><br>                                          |
| lung                         | basophilic change:bronchiole                                                                                                  | < 5><br>0 0 0<br>( 0) ( 0) ( 0) (            | <pre> &lt; 5&gt;<br/>0 5 0 0 0<br/>0) (100) ( 0) ( 0) ( 0)</pre>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | < 5><br>5 0 0 0<br>(100) ( 0) ( 0) ( 0)           | < 0><br>                                          |
| {Hematopoieti                | c system)                                                                                                                     |                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                   |                                                   |
| thymus                       | atrophy                                                                                                                       | < 5><br>0 0 0<br>( 0) ( 0) ( 0) (            | 0         4         0         0         0           0)         (80)         (0)         (0)         (0)         0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | < 5><br>5 0 0 0<br>(100) ( 0) ( 0) ( 0)           | < 0><br>                                          |
| spleen                       | deposit of melanin                                                                                                            | < 5><br>1 0 0<br>( 20) ( 0) ( 0) (           | <pre></pre>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)            | < 0><br>                                          |
| {Digestive sy                | vstem}                                                                                                                        |                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                   |                                                   |
| stomach                      | erosion:forestomach                                                                                                           | <pre>&lt; 5&gt; 0 0 0 ( 0) ( 0) ( 0) (</pre> | 0         1         0         0         0           0)         (20)         (0)         (0)         (0)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | < 5><br>0 1 0 0<br>( 0) ( 20) ( 0) ( 0)           | < 0><br>                                          |
| Grade<br>< a ><br>b<br>( c ) | 1 : Slight 2 : Moderate 3<br>a : Number of animals examined at the si<br>b : Number of animals with lesion<br>c : b / a * 100 | : Marked 4 : Severe<br>te                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                   |                                                   |

BAIS4

| REPORT TYPE<br>SEX           | : A1<br>: FEMALE                                                                                                             |                                                                                                                                                                                  |                                                   | PAGE : |
|------------------------------|------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|--------|
| Organ                        | Findings                                                                                                                     | Group Name         4000ppm           No. of Animals on Study         0           Grade         1         2         3         4           (%)         (%)         (%)         (%) | 8000ppm<br>0<br><u>1 2 3 4</u><br>(%) (%) (%) (%) |        |
| {Respiratory                 | y system}                                                                                                                    |                                                                                                                                                                                  |                                                   |        |
| nasal cavit                  | atrophy:olfactory epithelium                                                                                                 | < 0><br><br>( -) ( -) ( -) ( -)                                                                                                                                                  | < 0><br><br>( -) ( -) ( -) ( -)                   |        |
| lung                         | basophilic change:bronchiole                                                                                                 | < 0><br><br>( -) ( -) ( -) ( -)                                                                                                                                                  | < 0><br><br>( -) ( -) ( -) ( -)                   |        |
| {Hematopoie                  | ;ic system)                                                                                                                  |                                                                                                                                                                                  |                                                   |        |
| chymus                       | atrophy                                                                                                                      | < 0><br><br>( -) ( -) ( -) ( -)                                                                                                                                                  | < 0><br>                                          |        |
| spleen                       | deposit of melanin                                                                                                           | < 0><br>                                                                                                                                                                         | <pre>&lt; 0&gt; 0&gt;</pre>                       |        |
| {Digestive :                 | system)                                                                                                                      |                                                                                                                                                                                  |                                                   |        |
| stomach                      | erosion:forestomach                                                                                                          | < 0><br>( -) ( -) ( -) ( -)                                                                                                                                                      | < 0><br>                                          |        |
| Grade<br>< a ><br>b<br>( c ) | 1 : Slight 2 : Moderate 3<br>a : Number of animals examined at the s<br>b : Number of animals with lesion<br>c : b / a * 100 | : Marked 4 : Severe<br>ite                                                                                                                                                       |                                                   |        |

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS ( 3W)

 $\sim$ 

STUDY NO. : 0481

ANIMAL

: MOUSE Crj:BDF1

(HPT150)

### HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) SACRIFICED ANIMALS ( 3W)

#### STUDY NO. : 0481 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 SEX : FEMALE

| Organ                      |                                                                                                                               | Group Name         Control           No. of Animals on Study         5           Grade         1         2         3         4           (%)         (%)         (%)         (%) | 500ppm<br>5<br><u>1 2 3 4</u><br>(%) (%) (%) (%)             | 1000ppm<br>5<br><u>1 2 3 4</u><br>(%) (%) (%) (%) | 2000ppm<br>0<br><u>1 2 3 4</u><br>(%) (%) (%) (%) |
|----------------------------|-------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|---------------------------------------------------|---------------------------------------------------|
| {Digestive sys             | stem)                                                                                                                         |                                                                                                                                                                                  |                                                              |                                                   |                                                   |
| stomach                    | ulcer:forestomach                                                                                                             | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                                                                                                                           | < 5><br>1 0 0 0<br>( 20) ( 0) ( 0) ( 0)                      | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)            | < 0><br><br>( -) ( -) ( -) ( -)                   |
|                            | hyperplasia:forestomach                                                                                                       | 0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                                                                                                                                   | 0 3 0 0<br>( 0) ( 60) ( 0) ( 0)                              | 1 0 1 0<br>(20) (0) (20) (0)                      | ( -) ( -) ( -) ( -)                               |
| {Endocrine sy              | stem}                                                                                                                         |                                                                                                                                                                                  |                                                              |                                                   |                                                   |
| parathyroid                | cyst                                                                                                                          | $\langle 4 \rangle$<br>1 0 0 0<br>( 25) ( 0) ( 0) ( 0)                                                                                                                           | <pre> &lt; 5&gt;<br/>0 0 0 0<br/>( 0) ( 0) ( 0) ( 0)</pre>   | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)            | <pre> &lt; 0&gt;</pre>                            |
| adrenal                    | necrosis:cortex                                                                                                               | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)                                                                                                                                           | <pre> &lt; 5&gt;<br/>0 0 0 0<br/>( 0) ( 0) ( 0) ( 0)</pre>   | < 5><br>0 2 0 0<br>( 0) ( 40) ( 0) ( 0)           | < 0><br><br>( -) ( -) ( -) ( -)                   |
| {Reproductive              | system}                                                                                                                       |                                                                                                                                                                                  |                                                              |                                                   |                                                   |
| ovary                      | cyst                                                                                                                          | $\langle 5 \rangle$<br>1 0 0 0<br>( 20) ( 0) ( 0) ( 0)                                                                                                                           | <pre> &lt; 5&gt;<br/>0 0 0 0 0<br/>( 0) ( 0) ( 0) ( 0)</pre> | < 5><br>0 0 0 0<br>( 0) ( 0) ( 0) ( 0)            | < 0><br><br>( -) ( -) ( -) ( -)                   |
| Grado<br>< a ><br>b<br>(c) | 1 : Slight 2 : Moderate 3<br>a : Number of animals examined at the si<br>b : Number of animals with lesion<br>c : b / a * 100 | : Marked 4 : Severe<br>te                                                                                                                                                        |                                                              |                                                   |                                                   |

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# HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) SACRIFICED ANIMALS ( 3W)

STUDY NO.:0481ANIMAL:MOUSE Crj:BDF1REPORT TYPE:A1SEX:FEMALE

Group Name 4000ppm 8000ppm 0 0 No. of Animals on Study 2 3 3 Grade 4 4 1 (%) (%) (%) (%) (%) (%) (%) (%) Organ\_\_\_\_ Findings\_\_\_ {Digestive system} < 0> < 0> < 0> stomach ulcer:forestomach \_ \_ ( --) ( --) ( --) ( --) ( -) ( -) ( -) ( -) hyperplasia:forestomach ( --) ( --) ( --) ( --) ( --) ( --) {Endocrine system} < 0> parathyroid < 0> - - -- cyst (-) (-) (-) (-) ( -) ( -) ( -) ( -) < 0> < 0> adrenal - - necrosis:cortex ( -) ( -) ( -) ( -) ( -) ( -) ( -) ( -) {Reproductive system} < 0> ovary < 0> - - - cyst ( -) ( -) ( -) ( -) ( -) ( -) ( -) ( -) Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe

 $\langle \, a \, \rangle \qquad \ \ a$  : Number of animals examined at the site

b b : Number of animals with lesion

(c) c:b/a\*100

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## APPENDIX L

### METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-WEEK INHALATION STUDY OF 1-BROMOBUTANE

### METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-WEEK INHALATION STUDY OF 1-BROMOBUTANE

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

1) Automatic blood cell analyzer (ADVIA120 : Bayer Corporation)

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

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

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