1-ブロモ-3-クロロプロバンのラットを用いた 吸入によるがん原性試験報告書

試験番号:0417

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APPENDIX A 1

IDENTITY AND IMPURITY OF 1-BROMO-3-CHLOROPROPANEIN THE 2-YEAR INHALATION STUDY

IDENTITY AND IMPURITY OF 1-BROMO-3-CHLOROPROPANE IN THE 2-YEAR INHALATION STUDY

Test Substance : 1-Bromo-3-chloropropane (Wako Pure Chemical Industries, Ltd.)

A. Lot No. : SEJ4084

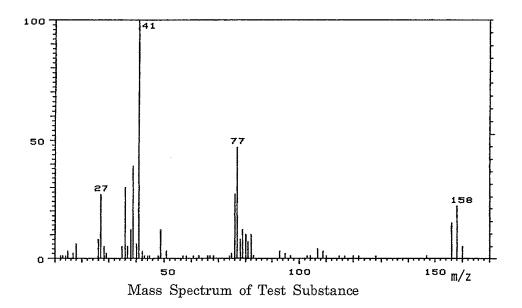
1. Spectral Data

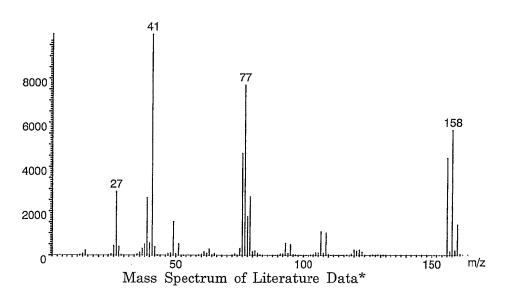
Mass Spectrometry

Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV





Result: The mass spectrum was consistent with literature spectrum.

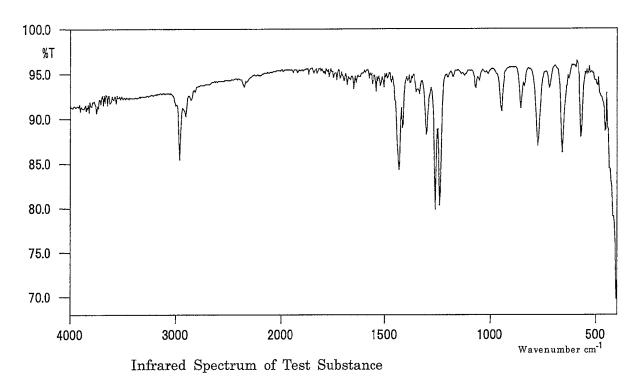
(*McLafferty FW, ed. 1994. Wiley Registry of Mass Spectral Data. 6th ed. New York, NY:John Wiley and Sons.)

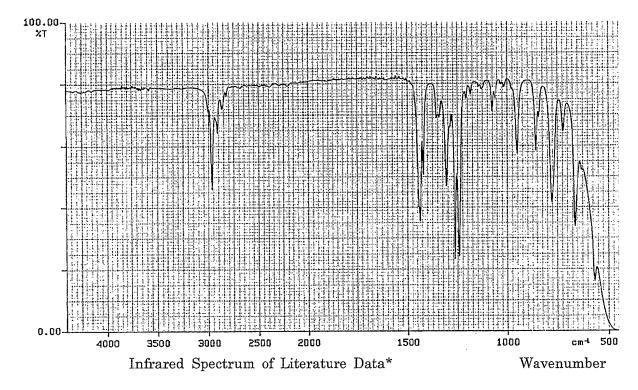
Infrared Spectrometry

Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 4 cm⁻¹





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

2. Impurity

Instrument

: Hewlett Packard 5890A Gas Chromatograph

Column

: Methyl Silicone (0.53 mm ϕ × 60 m)

Column Temperature: 100° C

Flow Rate

: 20 mL/min

Detector

: FID (Flame Ionization Detector)

Injection Volume

: 1 µL

Sample Name	Peak No.	Area (%)	Peak Name					
Test Substance		0.046	1,2-Epoxybutane					
	2	99.954	1-Bromo-3-chloropropane					

Result: Gas chromatography indicated one major peak (peak No. 2) and one impurity. It was identified by comparing GC-MS with that of 1,2-Epoxybutane (peak No. 1) in the 1-bromo-3-chloropropane. The amount in the test substance was 0.046%(The quantity value by the standard sample was 0.045%.) with a gas chromatograph.

3. Conclusion: The test substance was identified as 1-bromo-3-chloropropane by mass spectrum and infrared spectrum. Gas chromatography indicated one major peak(1-bromo-3-chloropropane) and one impurity. The impurity was 1,2-epoxybutane in the test substance.

B. Lot No.

: LDK4248

1. Spectral Data

Mass Spectrometry

Instrument

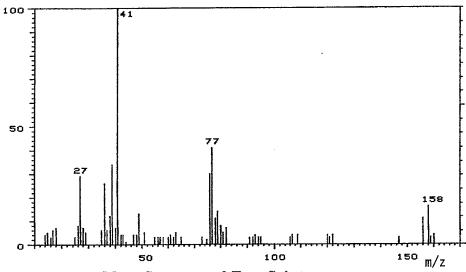
: Hitachi M-80B Mass Spectrometer

Ionization

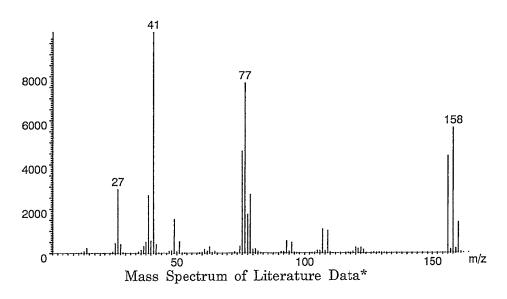
: EI (Electron Ionization)

Ionization Voltage

: 70eV



Mass Spectrum of Test Substance



Result: The mass spectrum was consistent with literature spectrum.

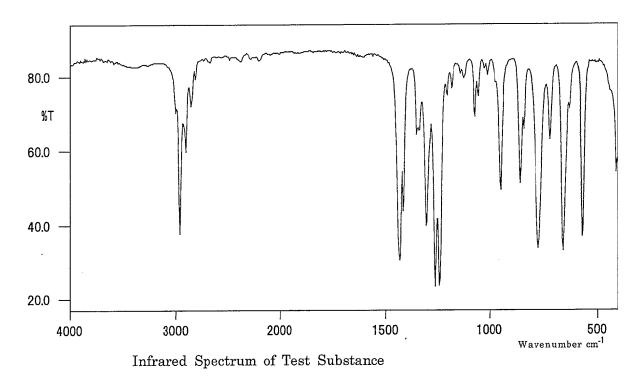
(*McLafferty FW, ed. 1994. Wiley Registry of Mass Spectral Data. 6th ed. New York, NY:John Wiley and Sons.)

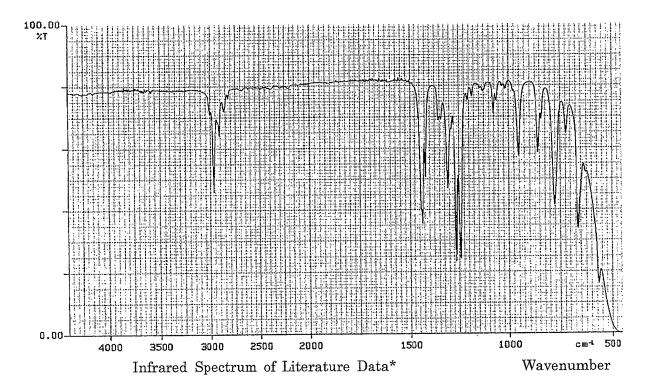
Infrared Spectrometry

Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 4 cm⁻¹





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

2. Impurity

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : Methyl Silicone (0.53 mm ϕ × 60 m)

Column Temperature: 100°C

Flow Rate : 20 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μL

Sample Name	Peak No.	Area (%)	Peak Name
Test Substance	1	0.046	1,2-Epoxybutane
	2	99.954	1-Bromo-3-chloropropane

Result: Gas chromatography indicated one major peak (peak No. 2) and one impurity. It was identified by comparing GC-MS with that of 1,2-Epoxybutane (peak No. 1) in the 1-bromo-3-chloropropane. The amount in the test substance was 0.046%(The quantity value by the standard sample was 0.045%.) with a gas chromatograph.

3. Conclusion: The test substance was identified as 1-bromo-3-chloropropane by mass spectrum and infrared spectrum. Gas chromatography indicated one major peak(1-bromo-3-chloropropane) and one impurity. The impurity was 1,2-epoxybutane in the test substance.

C. Lot No.

: WAN5724

1. Spectral Data

Mass Spectrometry

Instrument

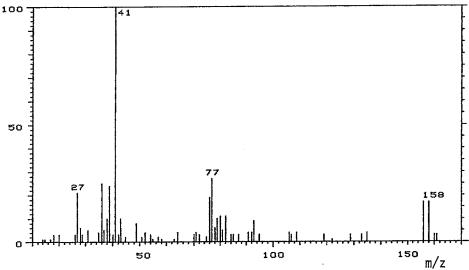
: Hitachi M-80B Mass Spectrometer

Ionization

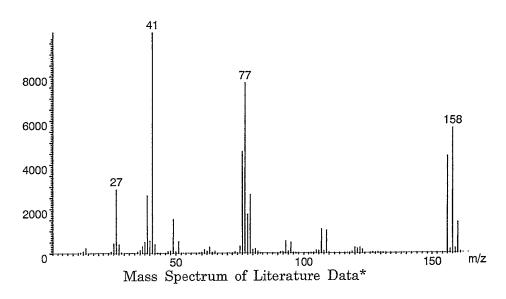
: EI (Electron Ionization)

Ionization Voltage

: 70eV



Mass Spectrum of Test Substance



Result: The mass spectrum was consistent with literature spectrum.

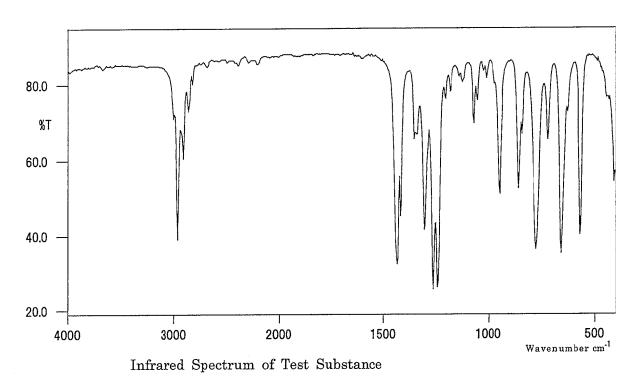
(*McLafferty FW, ed. 1994. Wiley Registry of Mass Spectral Data. 6th ed. New York, NY:John Wiley and Sons.)

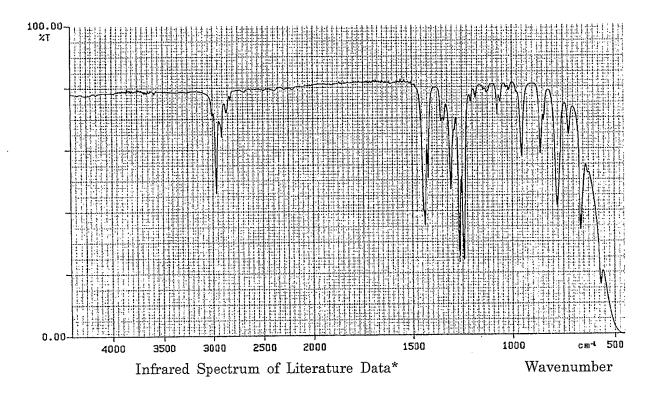
Infrared Spectrometry

Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 4 cm⁻¹





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

2. Impurity

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : Methyl Silicone (0.53 mm ϕ × 60 m)

Column Temperature: 100° C

Flow Rate : 20 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μL

Sample Name	Peak No.	Area (%)	Peak Name
Test Substance	1	0.041	1,2-Epoxybutane
	2	99.959	1-Bromo·3-chloropropane

Result: Gas chromatography indicated one major peak (peak No. 2) and one impurity. It was identified by comparing GC-MS with that of 1,2-Epoxybutane (peak No. 1) in the 1-bromo-3-chloropropane. The amount in the test substance was 0.041%(The quantity value by the standard sample was 0.041%.) with a gas chromatograph.

3. Conclusion: The test substance was identified as 1-bromo-3-chloropropane by mass spectrum and infrared spectrum. Gas chromatography indicated one major peak(1-bromo-3-chloropropane) and one impurity. The impurity was 1,2-epoxybutane in the test substance.

APPENDIX A 2

STABILITY OF 1-BROMO-3-CHLOROPROPANE IN THE 2-YEAR INHALATION STUDY

STABILITY OF 1-BROMO-3-CHLOROPROPANE IN THE 2-YEAR INHALATION STUDY

Test Substance

: 1-Bromo-3-chloropropane (Wako Pure Chemical Industries, Ltd.)

A. Lot No.

: SEJ4084

1. Sample

: This lot was used from 2000.11.7 to 2001.9.28. Test substance

was stored in a dark place at room temperature.

2. Gas Chromatography

Instrument

: Hewlett Packard 5890A Gas Chromatograph

Column

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

Column Temperature: 100°C

Flow Rate

: 20 mL/min

Detector

: FID (Flame Ionization Detector)

Injection Volume

: 1 µL

Date (date analyzed)	Peak No. Retention Time analyzed) (min)				
2000.11.06	1 2	1.828 6.667	0.046 99.954		
2001.10.02	$\frac{1}{2}$	1.827 6.659	0.059 99.941		

Result: Gas chromatography indicated one major peak (peak No. 2) and one impurity (peak No. 1 < 0.1% of total area) analyzed on 2000.11.6 and one major peak (peak No. 2) and one impurity (peak No. 1 < 0.1% of total area) analyzed on 2001.10.2. No new trace impurity peak in the test substance analyzed on 2001.10.2 was detected.

3. Conclusion: The test substance was stable for about 11 months in a dark place at room temperature.

B. Lot No.

: LDK4248

1. Sample

: This lot was used from 2001.10.1 to 2002.7.9. Test substance

was stored in a dark place at room temperature.

2. Gas Chromatography

Instrument

: Hewlett Packard 5890A Gas Chromatograph

Column

: Methyl Silicone (0.53 mm ϕ × 60 m)

Column Temperature: 100°C

Flow Rate

: 20 mL/min

Detector

: FID (Flame Ionization Detector)

Injection Volume

: 1 µL

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
2001.09.27	1	1.828	0.046
	2	6.665	99.954
2002.07.10	1	1.805	0.045
	2	6.611	99.955

Result: Gas chromatography indicated one major peak (peak No. 2) and one impurity (peak No. 1 < 0.1% of total area) analyzed on 2001.9.27 and one major peak (peak No. 2) and one impurity (peak No. 1 < 0.1% of total area) analyzed on 2002.7.10. No new trace impurity peak in the test substance analyzed on 2001.7.10 was detected.

3. Conclusion: The test substance was stable for about 9 months in a dark place at room temperature.

C. Lot No.

: WAN5724

1. Sample

: This lot was used from 2002.7.10 to 2002.11.1. Test substance $\,$

was stored in a dark place at room temperature.

2. Gas Chromatography

Instrument

: Hewlett Packard 5890A Gas Chromatograph

Column

: Methyl Silicone (0.53 mm ϕ × 60 m)

Column Temperature: 100°C

Flow Rate

: 20 mL/min

Detector

: FID (Flame Ionization Detector)

Injection Volume

: 1 µL

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
2002.07.09	1	1.806	0.041
	2	6.618	99.959
2002.12.10	1	1.806	0.041
	2	6.625	99.959

Result: Gas chromatography indicated one major peak (peak No. 2) and one impurity (peak No. 1 < 0.1% of total area) analyzed on 2002.7.9 and one major peak (peak No. 2) and one impurity (peak No. 1 < 0.1% of total area) analyzed on 2002.12.10. No new trace impurity peak in the test substance analyzed on 2002.12.10 was detected.

3. Conclusion: The test substance was stable for about 5 months in a dark place at room temperature.

APPENDIX B 1

CONCENTRATION OF 1-BROMO-3-CHLOROPROPANE IN THE INHALATION CHAMBETR OF THE 2-YEAR INHALATION STUDY

CONCENTRATION OF 1-BROMO-3-CHLOROPROPANE IN THE INHALATION CHAMBER OF THE 2-YEAR INHALATION STUDY

Group Name	Concentration(ppm) $Mean \pm S.D.$	
Control	0.0 ± 0.0	
25~ m ppm	$25.2 \pm \ 0.4$	
100 ppm	100.4 ± 0.9	
400 ppm	$400.1 \pm \ 3.6$	

APPENDIX B 2

ENVIRONMENTAL CONDITIONS OF INHALATION

CHAMBETR IN THE 2-YEAR INHALATION STUDY OF

1-BROMO-3-CHLOROPROPANE

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 2-YEAR INHALATION STUDY OF 1-BROMO-3-CHLOROPROPANE

	Temperature $(^{\circ}\!$	Humidity (%)	Ventilati (L/n		Air Change (time/h)			
Group Name	Mean \pm S.D.	Mean \pm S.D. Mean \pm S.D.* ¹ Mean \pm S.D.* ²		Mean \pm S.D.* ²	Mean*1	$Mean.*^2$		
Control	23.1 ± 0.1	57.2 ± 0.8	766.0 ± 4.4	1514.8 ± 21.8	6.0	12.0		
$25~\mathrm{ppm}$	23.2 ± 0.2	56.6 ± 1.5	765.1 ± 5.6	1526.7 ± 24.5	6.0	12.1		
100 ppm	23.1 ± 0.2	57.2 ± 0.8	765.6 ± 3.1	1525.8 ± 19.7	6.0	12.0		
$400~\mathrm{ppm}$	400 ppm 23.0 ± 0.1 56.5 ± 0.8		761.5 ± 2.9	1516.3 ± 20.3	6.0 12.0			

*1:Exposure period

*2:After exposure period

APPENDIX C 1

CLINICAL OBSERVATION: SUMMARY,

RAT: MALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-day											
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
реатн	O-1-4 1	0	•		_										
CAIII	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0		
	25ppm	0	0	Ö	Ö	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	ŏ	ő	0	0	0	0	0	•	-	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0 0	0	0	0	0
	**	-	-	•	v	v	v	v	v	U	U	U	0	0	0
OCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	Ö	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	Ŏ	0	Ö	0	0
	400ppm	0	0	0	0	0	0	0	0	Ö	ő	0	0	0	0
ATERAL		_												•	·
ATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	^	^	•	•	
	25ppm	0	Ŏ	Ö	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0			0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14 OMTO 10							•	Ů	Ü	U		V	U	U	U
ASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OILED	Control	0	0	0	0	0	^	^	•						
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0 0	0	0	0	0	0
	P.M.	-	•	J	v	v	U	U	U	U	0	0	0	0	0
ILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	Ö	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	Ö	0	0	0	0	0	0	-
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admin	istration P	eek-day _							···				
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	Control	•	•												
DENTII	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	^	0	•
	25ppm	0	0	0	Ō	0	Ö	0	0	0	0		0	0	0
	100ppm	0	0	Ö	0	0	0				-	0	0	0	0
	400ppm	Ö	0	0	0	0		0	0	0	0	0	0	0	0
	100ppiii	v	v	v	U	U	0	0	0	0	0	0	0	0	0
OCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	. 0	0	0	0	0	0	0	0	Ö
	100ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	0	0
	400ppm	0	0	0	0	0	0	0	0	0	Ö	0	0	0	0
ATERAL	Control	0	0	0	^		•	_							
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	23ppm 100ppm	0			0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	U	0	0	0	0	0	0	0	0	0	0	0	0	0
ARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	Ŏ	0	0	0	0	0	1
	100ppm	0	0	0	0	0	0	Ö	ő	Ö	0	0	0	-	-
	400ppm	0	0	0	0	0	ő	0	Ő	0	0	0	0	0	0
ASTING	Control	0	0	•	_								·	·	v
			-	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	. 0	0	0	0
DILED	Control	0	0	0	0	0	0	0	0	0	0	0	^	•	
	25ppm	0	0	Ö	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	Õ	Ö	0	0	0	0		-	0	0	0	0
	400ppm	0	Ö	ő	0	0	0	0	0	0	0	0	0	0 0	0
ILOERECTION	C+ 1	^			_				-	•	v	v	v	v	V
TPOPUGO I TOM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	ō
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-day											
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	1	1	1	1	1	1	1	1	1	2	2	2	2
	400ppm	0	0	1	1	1	1	1	1	1	1	1	1	1	1
ORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ö	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	. 0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	Ō	Ŏ	Ô	Ö	Ö	0
	100ppm	0	0	0	0	0	0	0	0	0	Ö	Õ	0	Ö	0
	400ppm	0	0	0	0	0	0	0	0	Ö	0	Ö	Ö	ő	0
ATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	-			0
	400ppm	0	ő	0	0	0	0	0	0	0	0	0 0	0 0	0 0	0 0
PARALYTIC GAIT	Control	0	0	0	0	0	^		•	•	•				_
AMEDITIO GILL	25ppm	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm 100ppm	0				0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	1	0	0	0	0	0	0	0	0	0	0	0	0	Ō
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
OILED	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	ō	Ö	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	Ö	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	Ö	ő	0	0	0	0	0
ILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	^
	25ppm	1	0	0	0	0	0	0	0	0	0	0	0		0
	100ppm	0	0	0	0	0	0	0	0		-	•	•	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	IIIQQQV E	v	v	v	U	U	U	U	U	0	0	0	0	0	0

STUDY NO. : 0417 CLINICAL OBSERVATION (SUMMARY)

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

SEX : MALE

Clinical sign	Group Name	Admin	istration W	eek-day _											
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
EATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	2
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	400ppm	1	2	2	2	2	2	2	2	2	2	2	2	2	2
ORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	1	1	1	1	1	1	1	1	1	1	ĺ	1	1	1
	100ppm	0	0	0	Ô	0	0	0	0	0	0	0	0	0	0
	400ppm	0	Ö	0	0	0	0	0	0	0	0	0	0	0	0
OCOMOTOR MOVEMENT DECR	0	^	^	^	•	•		_	_	_	-				
OCCUPATION MOVEMENT DECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	Ö	Ŏ	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0,	0	0	Ö	0	0	0	0	0
ARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	•		•
	25ppm	0	0	0	0	0	0	0		-		0	0	0	0
	100ppm	0	0			-	-	-	0	0	0	0	0	0	0
	100ppm 400ppm	0	0	0	0	0 0	0	0 0	0	0	0	0	0	0	0
	ınddoor	U	V	U	U	U	U	U	0	0	0	0	0	0	0
ASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	1	0	0	0	0	0	0	0	0	0	0	0	0	0
DILED	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	Ö	Õ	Ö	Õ	0	0	0	0	0	0	0		
	100ppm	Ö	Ö	0	0	0	0	0	0	0		-		0	0
	400ppm	0	Ö	0	0	0	0	0	0	0	0	0 0	0 0	0 0	0 0
ILOERECTION	Control	0	0	0	0	0	0	0	0						
	25ppm	0	0			0	0	0	0	0	0	0	0	0	0
			-	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0417 CLINICAL OBSERVATION (SUMMARY)

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

SEX : MALE PAGE: 5

Clinical sign	Group Name	Admini	stration W	eek-day											
	-	57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
												ac .			
EATH	Control	2	2	2	2	2	2	2	3	3	3	3	3	3	3
	25ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
	100ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	400ppm	2	2	2	2	2	2	2	2	2	3	3	3	3	3
ORIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	100ppm	0	0	Õ	0	0	0	0	0	Ô	0	0	0	0	0
	400ppm	0	0	0	Ö	0	0	0	0	0	0	0	0	0	0
OCOMOTOR MOMENTARIA DECE											-			_	
OCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	Ö	0	Ö	0	0	0	0	0	0	0	0	0		
	400ppm	Ö	0	Ö	0	0	0	0	0	0	0	0	0	0 0	0 0
ADALUTTA AATT											·	·	v	v	v
ARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	ō	Ö	0	Ö	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0			
	400ppm	0	Ö	0	0	0	0	0	0	0	0	0	0 0	.0 .0	0 0
OILED	0 - 1	^	•		•		2						-		
ATEM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	Ö	0	0	0	Ô	0	0	0	0
	100ppm	0	0	ŏ	Ŏ	Ö	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20000	•	v	· ·	v	V	v	v	v	v	U	U	U	U	U

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admin	istration W	/eek-day _											
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
ЕАТН	C1	9	9	0	4		,					_			
CAIII	Control 25ppm	3 1	3 1	3 1	4	4	4	4	4	4	4	5	5	5	6
					1	1	1	1	1	1	1	1	1	1	1
	100ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	400ppm	3	4	4	4	4	4	4	4	4	4	4	4	4	5
DRIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	25ppm	1	1	2	2	2	4	4	4	4	4	4	4	4	4
	100ppm	0	0	0	0	0	0	0	0	0	0	0	ō	1	1
	400ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
DOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	Ö	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	Ö	0	0	0	0	0	0	0	0	0
	400ppm	0	Ō	0	0	Ö	0	0	0	0	0	0	0	0	0
ATERAL	Control	0	0	0	0	^	^	•					_		
TIMED	25ppm	0	0	0	0 0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0 0	0 0	0 0	0	0 0	0 0	0 0	0	0 0	0
ARALYTIC GAIT	0 . 1	•		_								v	ŭ	v	v
ARALITIC GATT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
STING	Control	0	0	0	1	1	1	1	1	1	1	1	1	1	0
	25ppm	0	0	0	1	1	0	0	0	Ō	0	Ô	0	0	0
	100ppm	0	0	0	0	0	0	0	0	Ö	1	1	1	0	0
	400ppm	0	0	0	0	0	0	0	Õ	0	0	0	Ō	1	1
DILED	Control	0	0	0	0	0	0	0	0	0	0	0	0	^	^
	25ppm	Ŏ	Ö	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	-		0	0	0
	400ppm	Ö	0	0	0	0	0	0	0	0	0 0	0 0	0 0	0 0	0
ILOERECTION	Con+1	0	0	0	0	•	•	•					-	-	•
1202/00/110/1	Control		0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

STUDY NO. : 0417

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

SEX : MALE

linical sign	Group Name	Admin:	istration W	eek-day											
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
ЕАТН	C1		C		0	2	•				_				
DAIII	Control	6	6	6	6	6	6	6	6	6	6	6	7	7	7
	25ppm	1	1	1	2	2	3	3	3	3	3	3	4	4	4
	100ppm	2	3	3	3	3	3	3	3	3	3	3	4	4	4
	400ppm	5	5	5	5	5	5	5	5	5	6	6	6	6	8
ORIBUND SACRIFICE	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	25ppm	4	5	5	5	7	7	7	7	7	7	7	7	7	7
	100ppm	1	1	1	1	1	1	1	1	1	1	1	2	2	2
	400ppm	1	2	2	2	2	3	3	3	3	3	3	4	4	4
OCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	Ö	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	Ö	Ŏ	0	0	0	0	0	0	0	0	
	400ppm	Ö	0	0	0	0	0	0	0	0	0	0			1
	тоорры	V	v	U	U	U	U	U	U	U	U	U	0	0	0
ATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	Õ	0	0	0	0	Ö	0
	100ppm	0	0	0	0	0	0	0	Ō	0	Ö	0	0	1	2
	400ppm	0	0	0	0	0	Ō	0	Ö	0	0	0	0	0	0
ASTING	Control	0	0	0	0	0	0	0	0	0	0	0	^	•	
 · -	25ppm	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	25րիա 100թթm	0	0	0	_				0	0	0	0	0	0	0.
			0	0	0	0	0	0	0	0	0	0	0	0	2
	400ppm	1	U	U	0	0	0	0	0	0	0	0	0	0	0
OILED	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	Ö	0	0	ĺ	Ö	ő	0
	100ppm	0	0	0	0	0	0	0	0	0	Ô	Ô	Ŏ	0	0
	400ppm	0	0	0	0	0	0	0	0	Ö	0	0	ő	0	0
ILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	٥	0	^	
	25ppm	0	0	0	0	0				0	0	0	0	0	0
	23ppm 100ppm	0	0	0			0	0	0	0	0	0	0	0	0
					0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admin	istration	Week-day				_		 			
		99-7	100-7	101-7	102-7	103-7	104-7					- COLON	
		1	1	1	1	1	1						
				10.1.1				_					
DEATH	Control	7	7	7	9	9	9						
	25ppm	6	7	8	8	8	8						
	100ppm	6	6	7	7	8	8						
	400ppm	8	8	8	8	9	10						
MODIDININ CAODITION	a . 1												
MORIBUND SACRIFICE	Control	1	1	1	1_	1	1						
	25ppm	7	7	7	7	7	7						
	100ppm	3	4	4	4	4	4						
	400ppm	4	5	6	7	10	10						
OCOMOTOD MANENENT DECE	2						_						
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0						
	25ppm	0	0	0	0	0	0						
	100ppm	0	0	0	0	0	0						
	400ppm	0	0	0	0	0	0						
LATERAL	Control	0	0	0	0	0	0						
	25ppm	0	0	0									
					0	0	0						
	100ppm	0	0	0	0	0	0						
	400ppm	0	0	0	0	0	0						
PARALYTIC GAIT	Control	0	0	0	0	0	0						
	25ppm	0	0	0	0								
						0	0						
	100ppm	1	0	0	0	0	0						
	400ppm	0	0	0	0	0	0						
WASTING	Control	0	0	0	0	0	0						
	25ppm	0	0	0									
					0	0	0						
	100ppm	0	0	0	0	0	0						
	400ppm	0	0	0	0	0	0						
SOILED	Control	0	0	0	٥	0	^						
	25ppm	0	0	0	0	0	0						
	25ppm 100ppm				0	0	0						
		0	0	0	0	0	0						
	400ppm	0	0	0	0	0	0						
PILOERECTION	Control	0	0	0	0	0	0						
	25ppm	0	0	0	0	0	0						
	23ppm 100ppm	0	0	0									
	400ppm	0	0	0	0 0	0	0						
	mqqoor	U	U	U	U	0	0						

ANIMAL : RAT F344/DuCrj

REPORT TYPE: A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	A dms	ntantin W	1									 -		
oriniodi Sigii	aroub Mame	Admini 1-7	stration Wa 2-7	eek-day 3-7	4-7	5-7	6-7	7-7	8-7	0.7	10.7	11.2	16.5		
		1	1	1	1	1	1	1	1	9-7 1	10-7 1	11-7 1	12-7 1	13-7 1	14-7 1
								·	· · · · · · · · · · · · · · · · · · ·						
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	. 0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PROLAPSE OF ANUS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	Õ	Ö	0	Ö
	100ppm	0	0	0	0	0	0	0	0	0	Ŏ	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	Ö	0	0	0	0	0
SOILED PERI-GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	Ô	Ô	Ö	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	Õ	0	0	0	0	0	0	0
	100ppm	0	0	0	0	Ö	Ö	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	Ö	0	Ö	0	0	0	0	0
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	Ö	ő	o O	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	Ō	Ö	Ö	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	Ö	Ö	0	0	0	0	0
CATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	Õ	0	0	0	0	0
	100ppm	0	0	0	0	0	0	Ö	Ö	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	Ö	0	0	0	0
MYDRIASIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	^
	25ppm	0	0	Ö	Ö	Ö	0	0	0	0	0	0	0	0	0
	100ppm	0	0	Ō	ő	0	0	0	0	0	0	0	0	-	
	400ppm	0	0	Ō	0	0	0	0	0	0	0	0	0	0 0	0 0
ANTERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	
	100ppm	0	0	Ö	0	0	0	0	0	0	0	0	0		0
	400ppm	0	ō	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admin	istration W	/eek-day											
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DOG DELLA															
ROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ROLAPSE OF ANUS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	Ö	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	o o	0	0	0	0	0	0	0
DILED PERI-GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0		•
	25ppm	0	Ō	ő	0	ő	0	0	0	0	0		0	0	0
	100ppm	Ö	0	0	0	0	0	0			•	0	0	0	0
	400ppm	0	0	0	0				0	0	0	0	0	0	0
	#OODDIII	U	U	U	U	0	0	0	0	0	0	0	0	0	0
COPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ō
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
YE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	Ö	0	0	0	0	0	0	0
	100ppm	0	0	0	0	Ō	Ö	0	0	0	0	0	0		-
	400ppm	0	0	0	0	Ö	Ö	0	0	0	0	0	0	0 0	0
ATARACT	Control	0	0	0	0	0	٥	0	0	0	•				
	25ppm	0	0	0	0		0	0	0	0	0	0	0	0	0
	100ppm	0	0			0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1	1	1	1	1
	<i>ppm</i>	ŭ	v	J	V	v	V	U	U	U	0	0	0	0	0
DRIASIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	Ō	Ö	0	0	0	0	0
	100ppm	0	1	1	1	1	1	1	ì	I	1	1	1	1	
	400ppm	0	0	0	ō	ō	Ô	Ô	0	0	0	0	0	0	1 0
TERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	^			_	
	25ppm	0	ő	0	0	0	0			-	0	0	0	0	0
	100ppm	0	0	0	0	0		0	0	0	0	0	0	0	0
	400ppm	0	0	0			0	0	0	0	0	0	0	0 .	0
	Inddoor	U	U	U	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : Al 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : MALE

															PAGE :
Clinical sign	Group Name		istration V				7								
		29-7 1	30-7 1	31-7 1	32-7 1	33-7 1	34-7 1	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
					1	1		1	1	1	1	1	1	1	1
FROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	Ō	Ö	Ö	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0 0
PROLAPSE OF ANUS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	Ö	0	0	0	0
	100ppm	0	0	0	0	0	0	0	Ō	Ö	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	ō	0	0	0	0	0	0
SOILED PERI-GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	Ö	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	Ó	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0 -	0	0	Ö	0	0	0
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
	400ppm	0	0	0	0	0	0	0	0	ō	õ	0	0	0	0
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	Õ	0	ő	0	Ö
	100ppm	0	0	0	0	0	0	0	0	0	Õ	Ö	0	0	Ö
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	0	0
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400ppm	0	0	0	0	0	1	1	1	î	1	Î	1	1	1
YDRIASIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	Ö	0	0	0	0
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1 0
NTERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	. 0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	Ö	Ö	0	0	0	0	0	0	0
	400ppm	0	0	0	0	Ō	0	Ŏ	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admin:	istration W	eek-day											· · · · · · · · · · · · · · · · · · ·
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
חסק מפוניע															
ROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ROLAPSE OF ANUS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	Ö	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	Ö	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OILED PERI-GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	^	•	_
	25ppm	0	Õ	0	0	0	0	0	0	0	0	0 0	0	0	0
	100ppm	0	Ŏ	Ö	0	0	0	0		-	-	-	0	0	0
	400ppm	1	1	1	1	1			0	0	0	0	0	0	0
	100ррш	1	1	1	1	Ţ	1	1	1	1	1	1	1	1	1
KOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	1	1	1	1	1	1	1	1	1	1	1	i	2	2
	400ppm	0	0	0	0	0	0	0	0	0	0	ō	0	Ö	0
YE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	^	
	25ppm	0	0	0	0	0	0	0	0	0	0	0		0	0
	100ppm	0	0	Ō	0	0	0	0	0	0		-	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0 0	0 0
ATARACT	Control	0	0	^	0	^	•				-	•	·	v	v
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
					0	0	0	0	0	0	0	0	0	0	0
	100ppm	1	1	1	1	1	1	1	2	3	4	4	4	4	4
	400ppm	1	1	2	2	2	2	2	2	2	2	2	2	2	2
'DRIASIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	Ö	Ö	Ŏ	0	0
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	٥	0	^	•			
	25ppm	ő	0	0	0	0	0		0	0	0	0	0	0	0
	100ppm	0	0	0		-	-	0	0	0	0	0	0	0	0
	400ppm	0	0		0	0	0	0	0	0	0	0	0	0	0
	400hhm	U	U	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

Clinical sign	Group Name		istration V												
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		1	1	1	1		1	1	1	1	1	1	1	1	1
ROG BELLY	0	^	0	^	^	•	^	•	^	•	•				
ROG BELLI	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ROLAPSE OF ANUS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DILED PERI-GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	Õ	0	Ö	Ö	0	0	0	ő	Ö	Ö	0	0	0	0
	100ppm	0	0	ŏ	Õ	Ŏ	Ö	0	0	0	Ô	0	0	0	. 0
	400ppm	1	1	1	0	0	0	1	1	Ö	Ö	Ö	0	ő	0
KOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0			0
	100ppm	2	2	2	2	2	2						0	0	0
	400ppm	0	0	0	0	0	0	2 0	2 0	2 0	2 0	2	2 0	2 0	2 0
YE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	^	0	0
	25ppm	0	0	0	0	0	0	0	0	0		0	0	0	0
	100ppm	0	0	0			0	0			0	0	0	0	0
	100ppm 400ppm	0			0	0		-	0	0	0	0	0	0	0
	400pm	U	0	0	0	0	0	0	0	0	0	0	0	0	0
ATARACT	Control	0	0	0	0	0	0	1	1	1	1	1	1	1	1
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	4	4	4	4	4	4	4	4	5	5	5	6	6	6
	400ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
/DRIASIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400ppm	0	0	0	0	0	Õ	ō	ō	ô	0	Õ	0	0	0
NTERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	Ö	0	Ö	0	0	0	0	0	0	0	0	0
	100ppm	ō	0	Ö	0	1	0	0	0	0	0	0	0	0	0
	400ppm	Ö	0	0	0	0	0	0	0	0	0	0	0	0	0

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admin	istration W	leek-day _								-			
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DOG DELLA															
ROG BELLY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ROLAPSE OF ANUS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DILED PERI-GENITALIA	Control	0	0	0	0	0	0	1	1	1	1	1	1	1	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	1	1	0	Ö
	400ppm	1	1	1	1	0	0	0	0	0	0	1	1	1	1
KOPHTHALMOS	Control	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	25ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	100ppm	2	1	1	1	1	1	1	1	1	1	1	1	1	1
	400ppm	0	0	ō	0	0	0	0	0	0	0	0	0	0	0
YE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	1	1	1	Ô	Ö	0	Ŏ	Ö	ő	0	0	0	0	Ö
	100ppm	0	0	0	0	0	0	0	Ů	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATARACT	Control	1	1	1	1	1	1	2	2	2	2	1	1	1	1
	25ppm	0	Ō	0	2	2	2	2	2	2	2	2	-	_	1
	100ppm	6	6	6	6	6	6	6	6	6	6		2	2	2
	400ppm	2	2	2	2	2	2	2	2	2	2	6 2	6 2	5 2	5 2
'DRIASIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	^
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	_	0
	100ppm	1	0	0	0	0	0	0	0	0	0			0	0
	400ppm	0	0	0	0	0	0	0	0	. 0	0	0	0 0	0 0	0 0
NTERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	
······································	25ppm	0	0	0	0	0	0				-	0	0	0	0
	23ppm 100ppm	0	0	0				0	0	0	0	0	0	0	0
		0			0	0	0	0	1	1	1	1	1	0	0
	400ppm	U	0	0	0	0	0	0	0	0	0	0	0	0	0

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

STUDY NO. : 0417

SEX : MALE

linical sign	Group Name	Admin	istration W	leek-day _											
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		1	1	1	1	1	1	1 .	1	1	1	1	1	1	1
OG BELLY	Construct	^	•	^	^	•	•	•	•						
COG DELLI	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OLAPSE OF ANUS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	Ö	0	0	0	0	ő	0
OILED PERI-GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	Ŏ	Ö	1	0	0	0	0	0	0	0	0	0	0	1
	100ppm	0	0	0	0	0	0	0	0						
		2	1	1	1					0	0	0	0	1	1
	400ppm	4	1	1	Ŧ	1	1	1	1	1	1	1	1	1	1
OPHTHALMOS	Control	1	1	1	1	1	1	1	1	1	1	1	0	0	0
	25ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
E OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	1	1	1	1	1	1	1	1	1	0	Ö	2
	100ppm	0	0	0	0	0	0	0	0	Ô	0	0	0	0	
	400ppm	0	0	Ö	0	0	Ö	0	1	1	1	1	1	1	0 1
TARACT	Control	1	1	2	2	0	2	0	0	0	•			•	
	25ppm	2	2	3		2		2	2	2	2	2	1	2	2
					3	3	3	3	3	3	3	3	3	3	3
	100ppm	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	400ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
DRIASIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	Ö	Ô	Ö	0
	400ppm	0	0	0	0	0	0	ő	0	0	0	0	0	0	0
TERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	1	1	1	1	0	0	0
	25ppm	Ö	0	Ö	0	0	0	0	0	0	0	0			
	100ppm	0	0	0	0	0	0						0	0	0
	400ppm	0	0	0				0	0	0	0	0	0	0	0
	400ppm	U	U	U	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	A 2m = -		W1- 1						
orimical Sign	aroub Mame		istration		100.7	100 7	104.7			- "
		99-7 1	100-7	101-7	102-7	103-7	104-7			
		1	1	1	1	1	1			
FROG BELLY	Control	0	0	0	0	0	0			
	25ppm	0	0	0	0	0	0			
	100ppm	0	0	0	0	1	1			
	400ppm	0	0	0	0	0	0			
PROLAPSE OF ANUS	Control	0	0	0	0	0	0	•		
	25ppm	ő	0	0						
					0	1	1			
	100ppm	0	0	0	0	0	0			
	400ppm	0	0	0	0	1	1			
SOILED PERI-GENITALIA	Control	0	0	0	0	0	0			
	25ppm	0	0	0	0	0	0			
	100ppm	1	0	0	0	0	0			
	400ppm	1 .	1	1	1	ĺ	2			
XOPHTHALMOS	Control	0	0	0	0	٥	^			
	25ppm					0	0			
		0	0	0	0	1	1			
	100ppm	1	1	1	1	1	1			
	400ppm	0	0	0	0	0	0			
YE OPACITY	Control	0	0	0	0 .	0	0			
	25ppm	1	1	1	1	1	1			
	100ppm	0	0	0	0	Õ	0			
	400ppm	1	1	1	1	1	1			
TARACT	Control	2	2	2	2	2	9			
	25ppm	2	2				2			
				2	2	2	3			
	100ppm	5	5	5	5	5	5			
	400ppm	2	2	2	2	2	2			
YDRIASIS	Control	0	0	0	0	0	0			
	25ppm	0	0	0	0	0	Ō			
	100ppm	0	0	0	0	Ö	Ö			
	400ppm	0	o o	0	0	0	0			
NTERIOR CHAMBER OPACITY		•	_							
MIDATOR CHAMBER UPACITY	Control	0	0	0	0	0	0			
	25ppm	0	0	0	0	0	0			
	100ppm	0	0	0	0	0	0			
	400ppm	0	0	0	0	0	0			

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

SEX : MALE

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

Clinical sign Group Name Administration Week-day 1-7 2 - 73-7 4-7 5-7 6-7 7-7 8-7 9-7 10-7 11-7 12-7 13-7 14-7 EXTERNAL MASS Control 25ppm 100ppm 400ppm INTERNAL MASS Control 25ppm 100ppm 400ppm M. NOSE Control25ppm 100ppm 400ppm M. EYE Control 25ppm 100ppm 400ppm M. PERI-MOUTH Control 25ppm 100ppm 400ppm M. MANDIBULAR Control 25ppm 100ppm 400ppm M. EAR Control 25ppm 100ppm 400ppm M. PERI EAR Control 25ppm 100ppm 400ppm

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

ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admin	istration W	eek-day _											
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
CAMEDINAL MACC															
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	Control	0	0	0	0	0	^	^		•	_	_			
2	25ppm	0	0	0	0		0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	400ppm	0	0	0	0	0	0 0	0	0	0	0	0	0	0	0
	400իլու	U	U	U	U	U	U	0	0	0	0	0	0	0	0
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	Ö	Ö	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	Õ	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	Ő	0	0	0	0	0	0	0
v nyn										*	•	v	•	v	V
M. EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI-MOUTH	Control	0	0	0	0		•	•							
M. I DALL MOOTH	25ppm	0	0	0	0 0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0			0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0 0	0 0	0	0	0	0	0	0	0	0	0	0
	400pm	U	U	U	U	0	0	0	0	0	0	0	0	0	0
M. MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	^	•	^
	25ppm	0	Õ	Ö	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	Ö	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	Ŏ	Ö	0	0	0	0	0	0 0	0 0	0 0
M. EAR	a . •	^	•	_	_								•	•	•
in rull	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	Control	0	0	0	0	0	0	0	0	٥	0	^	^		_
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	-	0	0	0	0	0
	400ppm	ő	0	0	0	0	0	0		0	0	0	0	0	0
	230ppm	•	J	V	v	U	Ų	U	0	0	0	0	0	0	0

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

SEX : MALE

Clinical sign	Group Name	Admini	istration P	Yeek-day											
_		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40.7	41 77	40.7
		1	1	1	1	1	1	1	1	1	1	39-7 1	40-7 1	41-7 1	42-7
							*			<u> </u>		<u>.</u>	1	1	1
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	•	
	25ppm	0	0	1	2	1	2	2	1	1	1	1	0	1	1
	100ppm	0	Ö	0	0	0	0	0	0	0	0		1	1	1
	400ppm	0	0	0	0	. 0	0	0	0	0	0	0 0	0	0 0	0 0
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	1	0	0	Ö	0	0	0	0	0	0	0	0		0
	100ppm	Õ	Ö	0	0	0	0	0	0	0	0		•	0	0
	400ppm	Ö	Ö	Ö	0	0	0	0	0	0	0	0 0	0 0	0 0	0
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	^	•		
	25ppm	Ö	Ö	0	0	0	0	0	0	0	0	0	0	1	1
	100ppm	0	0	0	0	0	0				0	0	0	0	0
	400ppm	0	0	0	0	0		0	0 ,	0	0	0	0	0	0
	400pfii	U	U	U	U	U	0	0	0	0	0	0	0	0	0
M. EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	Õ	0	0	0	0	0
	100ppm	0	0	0	0	0	0	Ö	Ö	Ö	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	Ö	ő	0	0	0	0	0
M. PERI-MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	1	1	0	ī	1	Ö	0	0	0	0	0	0
	100ppm	0	0	0	0	0	Õ	0	Ŏ	0	0	0	0	0	
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0 0
M. MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	•	•	
	25ppm	0	Ö	0	0	0	0	0	0	0	-	0	0	0	0
	100ppm	Ō	ŏ	0	0	0	0	0			0	0	0	0	0
	400ppm	Ö	0	0	. 0	0	0	0	0 0	0 0	0 0	0 0	0	0	0 0
I. EAR	Control	0	0	0	0	0	0	0	0	•	0				
	25ppm	Ö	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	Ö	0	0	0	0				0	0	0	0	0	0
	400ppm	0	0	0	0	0	0 0	0	0	0 0	0	0 0	0	0	0 0
M. PERI EAR	Control	0	^	^	^				-				-	V	V
MAN A MAIL LILLIA		0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0.	0	0	0	0	0	0	0	0	. 0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

STUDY NO. : 0417

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admin	istration V	Yeek-day _											
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
EXTERNAL MASS	Control	1	2	2	2	3	3	3	3	3	3	3	3	3	3
	25ppm	1	1	1	2	3	3	3	3	4	4	4	3	3	3
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400ppm	0	0	0	0	0	0	0	1	1	1	2	2	2	2
NTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	^
	25ppm	Ō	ő	Ö	0	0	0	0	0			0	0	0	0
	100ppm	Ö	0	0	0	0	0			0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0 0	0	0	0	0	0	0	0
	Ισορριι	V	V	v	U	U	U	U	0	0	0	0	0	0	0
. NOSE	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	25ppm	0	0	0	0	0	0	0	0	ō	Õ	0	0	0	0
	100ppm	0	0	0	0	0	0	0	Ö	ő	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	Ö	0	0	0	0	0	0
EYE	Control	0	0	0	0	0	^		_						
	25ppm	0	0			0	0	0	0	0	0	0	0	0	0
				0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PERI-MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	Ö	0	Ö	0
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	
	400ppm	0	0	0	0	0	ō	Ô	0	Ô	0	1	1	1	1 1
MANDIBULAR	Control	0	0	0	0	0	0	^	•			_			
	25ppm	0	0	0			0	0	0	0	0	0	0	0	0
	100ppm	0	0		0	0	0	0	0	0	0	0	0	0	0
	400ppm	0		0	0	0	0	0	0	0	0	0	0	0	0
	Hddoot-	U	0	0	0	0	0	0	0	0	0	0	0	0	0
EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	100ppm	0	0	0	0	0	0	0	0	Ô	Ō	0	0	0	0
	400ppm	0	0	0	0	0	Ō	0	Ö	0	0	0	0	0	0
PERI EAR	Control	0	0	0	0	0	0	0	^	^	•				
	25ppm	0	0	0	0		0	0	0	0	0	0	0	0	0
	25ppm 100ppm	0				0	0	0	0	1	1	1	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0417 CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

SEX : MALE

DACE · O1

Clinical sign	Group Name	Admin	istration W	look-day											
	or out Transc	57-7	58-7	59-7	60-7	61-7	62-7	63-7	CA 7	CF 7	CC 17	25.5			
		1	1	1	1	1	1	1	64-7 1	65 - 7 1	66-7 1	67-7 1	68-7 1	69-7 1	70-7 1
XTERNAL MASS	Control	3	3	3	3	3	3	3	3	3	2	2	2	3	3
	25ppm	4	4	4	4	5	6	6	6	6	6	6	6	6	8
	100ppm	2	2	2	2	2	2	2	2	2	2	3	3	3	3
	400ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
NTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	^	•
	25ppm	0	0	0	0	0	0	0	0	0	0	•	0	0	0
	100ppm	0	Ŏ	0	0	0	0	0	0		•	0	0	0	0
	400ppm	0	0	Ö	0	0	0	0	0	0	0 0	0	0	0	0
LNOOP								· ·	v	v	v	U	v	v	U
. NOSE	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0 .	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0		^
	25ppm	0	0	0	Ō	0	Ö	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	ő	0	0	0	0	0 0	0 0	0
	400ppm	0	0	0	0	0	o o	ŏ	0	0	0	0	0	0	0
. PERI-MOUTH	Control	0	0	^	0	^	•		_						
WI ZHE MOOTH	25ppm	0	0	0 0	0 0	0	0	0	0	0	0	0	0	0	0
	100ppm	1	1	1		0	0	0	0	0	0	0	0	0	0
	400ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	MQQ00F	1	1	1	1	1	1	1	1	1	1	1	1	1	1
. MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	100ppm	0	0	0	0	0	0	0	0	0	ō	0	Ô	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EAR	Control	0	0	0	^	0	•	•							
	25ppm	1	1	1	0 1	0 1	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	1	1	1	1	1	1	1	1	1
	400ppm	0	0	0	0	0	0 0	0	0 0	0 0	0	0	0	0	0
DDDI DAD					-	•	Ť	•	•	V	U	U	U	U	0
PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ō
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	o o

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

STUDY NO. : 0417

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admin:	istration W	'eek-day _											
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		1	1	1	1	1	1	1	1	1	1	1		1	1
XTERNAL MASS	Control	3	4	3	3	3	3	3	4	4	4	4	4	5	5
	25ppm	8	7	6	6	7	6	6	7	7	7	8	8	8	8
	100ppm	2	3	4	4	4	5	5	6	6	6	6	6	5	5
	400ppm	2	2	2	2	2	3	3	3	3	3	3	3	3	4
NTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	25ppm	0	0	0	1	1	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. NOSE	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	25ppm	0	0	0	0	0	0	0	0	0	0	ō	Ō	Ō	0
	100ppm	0	0	0	0	0	0	0	0	Ō	0	0	Ŏ	Ö	Ö
	400ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	0	0
EYE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	100ppm	0	0	0	0	0	0	0	0	0	0	0			
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0 0	0 0
. PERI-MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	Ö	Ö	0	Ö	0	0	0	0	0	0	0	0	0	0
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1		
	400ppm	1	1	1	1	1	1	1	1	1	1	1	1	0 1	0 1
. MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	٥
· ALLIANDEDOLLIN	25ppm	1	0	0	0	0	0	0	0		-	-	-	-	0
	23ppm 100ppm	0							-	0	0	0	0	0	0
	100ppm 400ppm	0	0	0	0 0	0	0	0	0 0	0	0 0	0 0	0 0	0 0	0 0
. EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	1	1	1	1	1	1	1		1	1	1	1		1
	100ppm	0	0	0	0	0	0	0	. 1	0	0	0	_	1	_
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0 0	0 0
PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	^	^		
Will	25ppm	0	0			0	0	0	0	0	0	0	0	0	0
				0	0	1	1	1	1	1	1	1	1	1	1
	100ppm	0	0	1	1	1	2	2	2	2	2	2	2	2	2
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0417 CLINICAL OBSERVATION (SUMMARY) ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admin:	istration W	leek-day _											
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
KTERNAL MASS	Control	6	6	6	6	6	6	8	8	8	8	7	6	6	7
	25ppm	8	7	7	7	6	5	5	5	6	6	6	6	5	5
	100ppm	5	6	7	8	8	8	8	10	10	10	10	11	11	11
	400ppm	4	4	4	4	4	4	4	4	4	4	4	4	4	4
VTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	ō	0	0
NOSE	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	2
	25ppm	0	0	0	0	0	0	0	0	0	0	ō	0	Ō	0
	100ppm	0	0	0	0	0	0	0	Ō	0	Ö	Ö	Ŏ	Ö	0
	400ppm	0	Ō	0	Ö	0	Ö	0	0	0	0	0	0	0	0
ЕУЕ	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	100ppm	0	0	1	2	2	2	2	2	2	2	2	2		
	400ppm	0	Ö	0	0	0	0	0	0	0	0	0	0	2 0	2 0
PERI-MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	Ŏ	0	0	Ö	Ö	0	0	0	0	0	1	1	1
	100ppm	Ō	Ö	0	Ö	0	0	0	0	0	0	0	0	0	0
	400ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
. MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	^
	25ppm	0	0	0	0	0	0	0	0	0			0	0	0
	23ppm 100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0 0	0 0	0 0	0 0	0
EAR	Control	0	0	0	0	0	0	0	0	0	0	0	^	^	•
	25ppm	1	1	1	1	1	1	1	1	1	0 1	1	0	0	0
	100ppm	0	0	0	0	0	0	0	0		-		1	1	1
	400ppm	0	Ö	0	0	0	0	0	0	0 0	0	0 0	0 0	0 0	0 0
PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	^	0
	25ppm	1	1	1	1	0	0		-			-	-	0	0
	23ppm 100ppm	2	2	2	2			0	0	1	1	1	1	0	0
		0	0	0		2	2	2	2	2	2	2	2	2	2
	400ppm	U	U	υ	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admin	istration	Week-day _				
		99-7	100-7	101-7	102-7	103-7	104-7	
		1	1	1	1	1	1	
EXTERNAL MASS	Control	7	8	8	8	8	9	
	25ppm	4	5	5	7	7	10	
	100ppm	11	11	11	11	11	11	
	400ppm	4	4	3	5	4	4	
INTERNAL MASS	Control	0	0	1	2	2	2	
	25ppm	0	Ö	0	0	0	0	
	100ppm	0	0	0	0	0	0	
	400ppm	0	0	0	0	0	0	
I. NOSE	Control	2	2	2	2	2	2	
	25ppm	Õ	0	0	0	0	0	
	100ppm	Ö	0	0	0	0	0	
	400ppm	0	0	0				
	#00hm	U	U	U	0	0	0	
I. EYE	Control	0	0	0	0	0	0	
	25ppm	1	1	1	1	1	1	
	100ppm	2	2	2	2	2	2	
	400ppm	0	0	0	0	0	0	
I. PERI-MOUTH	Control	0	0	0	0	0	0	
	25ppm	0	0	0	0	0	0	
	100ppm	0	0	0	0	0	Ö	
	400ppm	1	1	1	2	2	2	
I. MANDIBULAR	Control	0	0	0	0	0	0	
	25ppm	Ô	0	0	0	0	0	
	100ppm	ő	0	0	0	0	0	
	400ppm	0	Ö	0	0	0	0	
. EAR	Control	0	0	0	0	0	0	
	25ppm	1	1					
	100ppm	0	0	1 0	1	1	1	
					0	0	0	
	400ppm	0	0	0	0	0	0	
. PERI EAR	Control	0	0	0	0	0	0	
	25ppm	0	0	0	0	0	Ö	
	100ppm	2	2	2	2	2	2	
	400ppm	0	0	0	1	1	1	
		-	•	•	-		*	

CLINICAL OBSERVATION (SUMMARY)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-day											
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
FORELIMB	0 1		•	•		_									
. FORELIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	- 0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	Ö	Õ	0	O O	0
	100ppm	0	0	Ō	Ö	Ö	Ŏ	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	Ö	0	0	0	0	0	0
ABDOMEN	Control	0	0	0	0	0	^	•	•	•		_			
1220,1231	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0			0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTERIOR. DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	Ŏ	0	0	Ö	0
	400ppm	0	0	0	0	0	0	0	0	0	ō	ő	0	0	0
INTERSCAPULUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	^	^
	25ppm	0	Õ	0	Ö	0	0	0	0	0	0	0	-	0	0
	100ppm	0	0	Ö	0	0	0	0	0		-		0	0	0
	400ppm	Ö	ő	0	0	0	0	0	0	0	0	0	0	0	0
POSTERIOR DORSUM	C	0	^	•	•	_						v	v	v	V
TOSTERIOR BORSOM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	Ö	0	Ö	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0			•	-
	400ppm	0	0	0	0	0	0	0	0	0	0	0 0	0	0 0	0 0
SCROTUM	Control	0	0	0	^	0				_			•	-	
- WOLLOW WILL				0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admin	istration Y	leek-day _		VIII		S							
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
. FORELIMB	0 1	•	•	•		_									
. PURELIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	Ō	0	0	o o	o
	400ppm	0	0	0	0	0	0	0	0	0	Ō	0	Ö	Ö	0
. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	Ö	0	0	0	0	0	0	0	0	0	0
	100ppm	0	Ö	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0				
	#400bfm	U	U	U	U	U	U	U	U	U	U	0	0	0	0
ANTERIOR. DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERSCAPULUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	Ō	0	Ŏ	Ö	0
	100ppm	0	0	0	0	0	0	Ō	Ö	Ö	Ö	Ö	Ŏ	0	0
	400ppm	0	Ō	0	0	Ö	0	ő	0	0	0	0	0	0	0
. POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	•	^	•	•	•	
	25ppm	0	0	0	0	0	0	-	0	0	0	0	0	0	0
	25ppm 100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0 0							
GENITALIA	Control 1	0	0	0	0	^	0	•	•			_			
. OPMITAPIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. SCROTUM	Control	0	0	-0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	Ō	0	Ō	Ö
	100ppm	0	0	0	0	0	0	0	Ö	ő	Ö	Ö	0	ů	0
	400ppm	0	0	0	0	0	0	0	0	ō	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

Clinical sign	Group Name		istration !											4	
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
FORELIMB	Control	0	0	0	0	0	٥	^	•	•	•			_	
TORELIND	25ppm	0	0	0	1	0 1	0 1	0 1	0 1	0	0	0	0	0	0
	23ppm 100ppm	0	0	0	0	0		_	_	1	1	1	1	1	1
	400ppm	0	0	0	0	0	0 0	0 0	0 0	0	0 0	0	0 0	0 0	0 0
BREAST		^	0	0	^	•					·				
DKEASI	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	. 0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTERIOR. DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ō
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ō
INTERSCAPULUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	Ö	0	0	o o	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ő	0
POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	•
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0 0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0		0
	400ppm	0	Ö	0	0	0	0	0	0	0	0	0	0	0 0	0 0
GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	•	•	•
	25ppm	0	0	. 0	0	0	0	0	0	0	0	•	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	-	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0 0	0	0	0	0
SCROTUM	Control	0	0	0	0	0	0	•	^	•	•				
DOMO I OM	Control		0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	. 0
	100ppm	0	0	0	0	0	Ö	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

Clinical sign	Group Name		istration V												
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
		1	1	1	1	1	1	1	1	1	1	1	1	I	1
. FORELIMB	Control	0	0	0	0	0	0	0	0	0	0	0	^	0	•
a i Ordinin	25ppm	1	1	1	1	1	1	1	1	1	1	0 1	0	0 1	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1 0
	400ppm	Ö	Ö	0	ő	0	0	0	0	0	0	0	0	0	0
. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. ABDOMEN	Control	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTERIOR. DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	1	1	1	1	1	1	1	1	1	1	1
	100թթա	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. INTERSCAPULUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
L POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	1
GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. SCROTUM	Control	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

C1:-:-1 .:	4 37														
Clinical sign	Group Name		istration W						·						
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
(Danny												•			
M. FORELIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	1	1	1	1	1	1	1	1	2
	100ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	1
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ō
M. ABDOMEN	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
A. ANTERIOR. DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	100ppm	0	0	0	0	0	0	0	0	0	0	0	ō	0	ō
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	ō
M. INTERSCAPULUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ő	0
	400ppm	0	0	0	0	. 0	0	0	0	0	0	0	0	0	Ŏ
A. POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	25ppm	0	0	0	0	1	1	1	1	1	1	i	1	1	î
	100ppm	1	1	1	1	1	1	1	1	1	ī	1	1	1	î
	400ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
M. GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	ŏ	ő	0	0	0
	100ppm	0	0	0	0	0	0	0	Ö	0	Ŏ	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	Ö	ő	0	0	0	0
M. SCROTUM	Control	1	1	1	1	1	1	1	1	1	0	0	0	0	0
	25ppm	0	0	0	0	0	0	Ō	0	0	0	0	0	0	0
	100ppm	0	0	Ō	ő	Ö	ő	0	Ő	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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

ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admin	istration W	/eek-day _											
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
I. FORELIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	100ppm	0	0	0	0	0	0	0	1	1	1	ī	1	1	1
	400ppm	0	0	0	0	0	0	0	0	0	Õ	Ô	ō	0	0
. ABDOMEN	Control	1	1	1	1	1	1	1	2	2	2	2	2	2	2
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	1	1	1	1	1	1	i	1	1	1	1		
	400ppm	0	0	Õ	ō	0	0	0	Ô	Ô	0	0	0	1 0	1
ANTERIOR. DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	•	
	25ppm	1	1	í	1	1	0	0	0		-		0	1	1
	100ppm	0	0	0	0	0		-		0	0	1	1	1	1
	400ppm	0	0	0	0	0	0 0	0 0	0 0	0 0	0	0 0	0 0	0 0	0 0
. INTERSCAPULUM	Control	0	0	0	0	0	0	0	•	0		•	•		
	25ppm	1	1	0	0	0	0		0	0	0	0	0	0	0
	100ppm	0	0				=	0	0	0	0	0	0	0	0
	400ppm	0	0	0 0	0 0	0	0	0 0	0 0	0 0	0 0	0	0 0	0 0	0 0
POSTERIOR DORSUM									V	V	v	v	V	U	U
POSTERIOR DORSON	Control	1	1	1	1	1	1	1 .	1	1	1	1	1	1	1
	25ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ô
	100ppm	0	0	0	0	0	0	0	0	0	Ö	0	Ö	0	Ö
	400ppm	0	0	0	0	0	1	1	1	1	1	1	1	1	1
SCROTUM	Control	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	Ō	ō	0	0	0	0	0	0	0	
	100ppm	0	0	0	Ö	Ŏ	0	0	0	0	0	0	-		0
	400ppm	0	Ŏ	Ö	0	0	0	0	0	0	0	0	0	0	0
	2- oppm	•	v	Ü	•	U	V	U	U	U	U	U	0	0	0

ANIMAL : RAT F344/DuCrj

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Carrier Name	A 7 *		. 1 1											
TIMICAL SIGN	Group Name		istration V												
		85-7 1	86-7 1	87-7 1	88-7 1	89-7 1	90-7 1	91-7 1	92-7 1	93-7 1	94-7 1	95-7 1	96-7 1	97-7 1	98-7 1
										·					
FORELIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	100ppm	0	0	0	0	0	0	0	0	0	0	Ō	Ô	Ô	Ô
	400ppm	0	0	0	0	0	0	0	Ō	Ö	0	0	0	0	0
. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	2	1	1	1	1	0	0	0	0	0	0	0	0	0
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1		
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	1 0	1 0
I. ABDOMEN	Control	2	2	2	2	2	2	2	2	2	2	2	1	1	1
	25ppm	0	0	0	0	0	0	Õ	0	0	0	0	0	0	0
	100ppm	1	2	2	2	2	2	2	3	3	3	3			
	400ppm	1	1	1	1	0	0	0	0	0	0	0	3 0	3 0	3 0
. ANTERIOR. DORSUM	Control	2	2	2	2	2	2	4	4	4	4	3		•	
	25ppm	1	1	1	1	1	1	1	1	1		-	3	3	3
	100ppm	0	0	0	0	0	0	0	0		1	1	1	1	1
	400ppm	0	Ö	0	0	0	0	0	0	0 0	0 0	0 0	0 0	0 0	0 0
. INTERSCAPULUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	Ö	0	0	0	0	0	0	0	0			0
	100ppm	0	0	Ö	0	0	0	0	0	-		-	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0 0	0 0	0 0	0 0	0 0
. POSTERIOR DORSUM	Control	1	1	1	1	1	1	1	1	1	1	•	,		
	25ppm	1	ī	1	1	1	1	1		_	1	1	1	1	1
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400ppm	1	1	1	2	2	2	2	2 2	2 2	2 2	2 2	3 2	3 2	3 2
. GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	•		
	25ppm	0	0	0	0	0	0	0	0	0	-	-	0	0	0
	100ppm	o O	0	0	0	0	0	0	0		0	0	0	0	0
	400ppm	1	1	1	1	1	1	1	1	0 1	0 1	0 1	0 1	0 1	0 1
. SCROTUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	•	_
	25ppm	Ö	Ö	0	0	0		0			•	0	0	0	0
	100ppm	0	0	0			0	=	0	0	0	0	0	0	0
		0	0		0	0	0	0	0	0	0	0	0	0	0
	400ppm	U	U	0	0	0	0	0	0	0	0	0	0	0	0

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

ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admin	istration	Week-day					
<u>-</u>		99-7	100-7	101-7	102-7	103-7	104-7	 	
		1	1	1	1	• 1	1		
								 	
. FORELIMB	Control	0	0	O	0	0	0		
. I ONDERNO	25ppm	1	1	1	1	0	0		
	100ppm	0	0			1	1		
		0	0	0	0	0	0		
	400ppm	Ų	U	U	0	0	0		
. BREAST	Control	0	0	0	0	0	0		
	25ppm	0	1	1	1	1	1		
	100ppm	1	1	1	1	1	1		
	400ppm	Õ	Ô	o o	0	0	0		
				-	•	-	•		
. ABDOMEN	Control	1	2	2	2	2	2		
	25ppm	0	0	0	2	2	4		
	100ppm	3	3	3	3	3	3		
	400ppm	0	0	0	0	1	1		
. ANTERIOR. DORSUM	Control	3	3	3	0	0	0		
THE DATE OF THE PORT OF THE PO	25ppm	0	0		3	3	3		
				0	0	0	0		
	100ppm	0	0	0	0	0	0		
	400ppm	0	0	0	0	0	0		
INTERSCAPULUM	Control	0	0	0	0	0	0		
	25ppm	0	0	0	0	0	0		
	100ppm	0	0	0	0	0	0		
	400ppm	0	0	0	0	0	0		
POSTERIOR DORSUM	Control	1	1	1	1	1	1		
	25ppm	1				1	1		
		3	1	1	1	1	2		
	100ppm 400ppm	2	$\frac{3}{2}$	3 1	3 1	3 0	3		
	ունգնու <u>բ</u>	4	4	1	1	U	0		
GENITALIA	Control	0	0	0	0	0	0		
	25ppm	0	0	0	0	0	0		
	100ppm	0	0	0	0	0	0		
	400ppm	1	1	1	1	0	0		
. SCROTUM	Control	0	٥	0	0	•	•		
			0	0	0	0	1		
	25ppm	0	0	0	0	0	0		
	100ppm	0	0	0	0	0	0		
	400ppm	0	0	0	0	0	0		

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

SEX : MALE

Clinical sign	Group Name	Admini	stration W	ook-day											
	or orb Hame	1-7	2-7	еек-цау <u> </u>	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	19_7	19.7	14.7
		1	1	1	1	1	1	1	1	9-7 1	10-7	11-1	12-7 1	13-7 1	14-7 1
						-		-	*						<u>.</u>
ANEMIA	Control	0	^	0	^	0	•	•							
HILLINIA	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CRUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	Ō	0	Ō	Ö	Ö	Ö	0	0
	400ppm	0	0	0	0	0	0	0	0	Ō	Ö	Ö	Ö	0	0
HEMORRHAGE	Control	0	0	0	0	0	0	•			^	•	•		
11DROKIGE10D	25ppm	0	0	0			0	0	0	0	0	0	0	0	0
					0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PROLAPSE OF PENIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	Õ	Ö
	100ppm	0	0	0	0	0	0	0	0	0	0	0	Ŏ	0	ŏ
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ö	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	^
	25ppm	Ö	0	0	0	0	0	0	0	0	0	0			0
	100ppm	0	0	0	0	0	0	=	-	-	•	-	0	0	0
		0	0					0	0	0	0	0	0	0	0
	400ppm	U	U	0	0	0 .	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ö	Ŏ
TACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	•
×	25ppm	0	0	0	0	0	0	0	0	0		-	0	0	0
	100ppm	0	0	0	0		0			-	0	0	0	0	0
	400ppm	0	0	0	. 0	0	0	0	0	0	0 0	0 0	0 0	0 0	0 0
D. 200			-			•	•	v	•	V	v	v	v	U	v
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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

SEX : MALE

Clinical sign	Group Name	Admini	stration W	eek-day											
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
												•			
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	Ô	0	0	0	0
	100ppm	0	0	0	0	0	0	Ö	Ö	0	0	Ů	0	0	0
	400ppm	0	0	0	0	0	Ō	o o	ŏ	ő	ő	0	0	0	0
IEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	. 0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	Õ	0	Ö	0	0	0
	100ppm	0	0	0	0	0	0	Ö	ŏ	0	0	0	0	0	
	400ppm	0	0	0	0	Ö	Ö	0	0	0	0	0	0	0	0 0
ROLAPSE OF PENIS	Control	0	0	0	0	0	0	0	0	0	0	0	^	•	^
	25ppm	0	Õ	0	0	0	0	0	0				0	0	0
	100ppm	0	Ö	0	0	0	0	-	-	0	0	0	0	0	0
	400ppm	0	ő	0	0	0	0	0 0							
RREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	•	•	•
	25ppm	Ŏ	Õ	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	Ö	0	0	0	0	0	-	-	-	•	0	0	0	0
	400ppm	0	0	0	0	0	0	0 0	0 0	0 -	0 0	0 0	0 0	0	0 0
BNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0		
	25ppm	0	0	0	0	0	0	0	-	•	-	0	0	0	0
	100ppm	0	0	0	0	0	0		0	0	0	0	0	0	0
	400ppm	ő	0	0	0	0	0	0 0	0	0 0	0 0	0 0	0	0	0 0
ACHYPNEA	Control	0	0	0	. 0	0	0	0	0	0	•				_
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0				0	•	0	0	0	0	0	0
	400ppm	0	0	0	0 0	0 0	0 0	0	0 0	0 0	0 0	0	0	0	0
EEP BREATHING	Control	0	0	0	0	0	0	0	^	0	-				
	25ppm	0	0	0			0	0	0	0	0	0	0	0	. 0
	23ppm 100ppm	0	0		0	0	0	0	0	0	0	0	0	0	0
				0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admin	istration W	Veek-day _											
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
JITHET A	0 . 1	•			_										
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	Ö	0	0	0	0
	100ppm	0	0	0	0	Ō	Ö	0	o ·	0	0	0	0	0	0
	400ppm	0	0	0	0	0	Ö	0	0	0	0	0	0	0	0
EMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0		•		
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0					0	0	0	0	0	0	0
		0	-	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	U	0	U	0	0	0	0	0	0	0	0	0	0	0
ROLAPSE OF PENIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	Ö	0	Ô	0	0	0	0	
	100ppm	0	0	0	0	0	0	Ŏ	0	0	0	0			0
	400ppm	Ō	Ö	0	0	0	0	0	0	0	0	0	0 0	0	0 1
BNORMAL RESPIRATION	Control 1	0	0	0	^	•			_					·	_
	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	-	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm		0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	0	Ö
	100ppm	0	0	0	0	0	0	0	0	0	1	Ö	0	Ö	0
	400ppm	0	0	0	0	0	0	0	Ô	ō	0	0	0	0	0
SEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	^	0	
	25ppm	Ö	Ö	0	0	0	0	0	0	0	-		0	0	0
	100ppm	0	0	0	0	0	0	0		-	0	0	0	0	0 .
	400ppm	0	0	0	0	0	0		0	0	0	0	0	0	0
	mddoor-	v	U	U	U	U	U	0	0	0	0	0	0	0	0

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

SEX : MALE

linical sign	Group Name	Admin:	istration W	leek-day _											
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	. 0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ō
ROLAPSE OF PENIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	ō	ō	Ö	o o	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	0	ō
RREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	. 0	0	0	0	0	0	Ö
	400ppm	1	0	0	0	0	0	0	0	0	0	0	ő	0	0
BNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	Ŏ	0	Ö	0
	100ppm	0	0	0	0	ő	Ö	0	Ö	0	0	0	0	0	0
	400ppm	0	0	ō	Ō	0	0	0	0	0	0	0	0	0	0
ACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	Ō	0	0	0	0	0	0	0	Ŏ	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	Ö	0	0	0	0	0	0	0	0	0	0	0		-
	400ppm	Ő	0	0	0	0								0	0
	40Uppm	U	U	U	υ	U	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS REPORT TYPE : A1 104

SEX : MALE

Clinical sign	Group Name	Admini	istration W	eek-day _											
•		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
ATPMT 4															
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	1	1	1	1	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	. 0	0	0	0	0	0	. 0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	Õ	Ö	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	Ö	ő	0	0	0	0
ROLAPSE OF PENIS	Control	0	0	0	0	0	0	0	0	0	0	0	0		0
	25ppm	0	0	Ö	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	Ö	Ö	0	0	0	0	0	0	0	0	0	-	0
	400ppm	0	0	0	0	0	Ö	0	0	0	0	0	0	0 0	0 0
RREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	^		
	25ppm	0	0	ő	0	0	0	1	1	1	0		0	0	0
	100ppm	0	0	0	0	0	0	0	-	-		0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0 0	0	0	0	0 0	0
BNORMAL RESPIRATION	Control	0	0	0	0	0	0	•	^	•			_		
A COLUMN TO THE PARTY OF THE PA	25ppm	0	0	0	0	-	0	0	0	0	0	0	0	0	0
	23ppm 100ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0 0	0 0	0 0	0	0 0	0 0	0 0	0 0	0	0 · 0	0
ACHYPNEA	Control	0	0	0	0	0							-		
	25ppm	0	0	0 0	0	0	0	0	0	0	0	0	0	0	0
	25ppm 100ppm	0			0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0 0	0 0	0	0 0	0 0	0	0 0	0	0 0	0	0 0	0	0
BEP BREATHING	Camer 1	0	0	•	•	•						·	-	•	V
TO THE THE TANK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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

SEX : MALE

Clinical sign	Group Name	Admin	istration W	eek-day _											
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
NEMIA		•	•		_										
INEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	^	^	•
	25ppm	0	Ö	0	0	0	0	0	0	0		0	0	0	0
	100ppm	0	0	0	0	0	0		•		0	0	0	0	0
	400ppm	0	0	0	0	0		0	0	0	0	0	0	0	0
	#00bbtt	U	U	U	U	U	0	0	0	0	0	0	0	0	0
EMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	Ŏ	Ô	0	0	0	0	0	0
	100ppm	0	0	0	0	0	ō	o O	0	0	0	0	-		
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		•	•	·	•	U	V	v	U	V	U	U	U	0	0
ROLAPSE OF PENIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	1	0	0	0	0	0	0	Ö	0	0	0	0
	100ppm	0	0	0	0	0	Ō	o	0	0	Ů	0	0	0	0
	400ppm	0	0	0	0	0	0	0	Ö	0	0	0	0	0	0
RREGULAR BREATHING	0 - 4- 1	^	•		_										
KKEGGEAK DREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	2	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	^	^			_		
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0			0	0	0	0	0	0	0	0
	400ppm	1	0	0	0	0	0 0	0	0 0	0 0	0	0	0	0	0
	~~ Abm	•	v	Ū	V	V	V	U	U	U	0	0	0	0	0
ACHYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	Ō	0	0	Ö	0	0	0	0	0	0	0
	100ppm	0	0	0	0	Ō	0	0	0	0	0	0			•
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0 0
BEP BREATHING	0										-	•	•	•	•
TO DEPOSITE OF THE PARTY OF THE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX: MALE

Clinical sign	Group Name	Admini	stration W	leek-day											
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
NEMIA	Control	0	0	0	0	1	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	1	0	0	0	0	0	0	0	0	Ö
	100ppm	1	0	0	0	0	0	0	0	0	0	0	0	0	Ö
	400ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
RUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	Ō	0	Ö	0	0	0	0	0	0
	100ppm	0	0	Ö	Ö	0	Ô	0	0	0	0	0	0	0	0
	400ppm	0	Ö	0	0	Ö	Ö	0	0	0	0	0	0	0	0
EMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0		0
	100ppm	0	0	Ö	0	0	0	0	0	0	-	-	-	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0 0	0	0	0	0
	100ррш	-	V	V	v	v	U	U	U	U	U	0	0	0	0
ROLAPSE OF PENIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ō	Ö
	100ppm	0	0	0	0	0	0	1	1	0	0	Ö	ì	1	1
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ô
RREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	o O	Õ	Ö	0	0	0	0	0
	100ppm	0	0	0	0	0	Ö	0	0	0	0	0	0		
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	1
BNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	^	•	•	
	25ppm	0	Ō	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	Ō	0	0	0	0	0	0	0	0	•	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0 0	0 0	0 0	0	0
ACHYPNEA	Control	0	0	0	0	0	0	^	•	•		_	_	•	
	25ppm	0	0	0	0	0		0	0	0	0	0	0	0	0
	100ppm	0	0	0			0	0	0	0	0	0	0	0	0
	100ppm 400ppm	0	0		0	0	0	0	0	0	0	0	0	0	0
	mqqvvr	U	U	0	0	0	0	0	0	0	0	0	0	0	0
SEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	Ō	ō	ő	0	0	0
	400ppm	1	0	0	0	0	0	0	0	Ō	0	0	0	Ö	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

1112 111

SEX : MALE

linical sign	Group Name	Admin	istration '	Week-day									
	or oab route	99-7	100-7	101-7	102-7	103-7	104-7	_					
		1	1	101-7	102-7	103-7							
				1		1	1	-					
NEMIA	Control	0	0	0	0	1	1						
	25ppm	0	0	0	0	0	0						
	100ppm	0	0	0	0	0	1						
	400ppm	0	1	1	1	0	0						
RUSTA	Control	1	1	1	1	1	1						
	25ppm	ō	0	0	0	0	0						
	100ppm	0	0	0	0	0	0						
	400ppm	0	0	0	0	0	0						
	#AAAhiii	0	U	V	U	Ų	U						
EMORRHAGE	Control	0	0	0	0	0	0						
	25ppm	0	1	0	0	0	0						
	100ppm	0	0	0	1	0	0						
	400ppm	0	0	0	0	0	0						
ROLAPSE OF PENIS	Control	0	0	0	0	0	0						
	25ppm	0	0	0									
	25ppm 100ppm	1	0	0	0	0	0						
	400ppm	0	0	0	0 1	0	0						
	inddoor	U	U	U	1	0	0						
RREGULAR BREATHING	Control	0	0	0	0	0	0						
	25ppm	0	0	0	0	0	0						
	100ppm	0	0	0	0	0	0						
	400ppm	0	0	0	0	0	0						
BNORMAL RESPIRATION	Control	0	0	0	0	0	0						
	25ppm	0	0	0	0	0 0	0						
	100ppm	0	0	0			0						
	400ppm	0	0	0	0	0	0						
	400htti	U	U	U	U	0	0						
ACHYPNEA	Control	0	0	0	0	0	0						
	25ppm	0	0	0	0	0	0						
	100ppm	0	0	0	0	0	Ö						
	400ppm	0	0	0	0	. 0	0						
EEP BREATHING	<i>(</i>	^	^	^	•	•							
DITUTION DISTRICTION	Control	0	0	0	0	0	0						
	25ppm	0	0	0	0	0	0						
	100ppm	0	0	0	0	0	0						
	400ppm	0	0	0	0	0	0						

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

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Clinical sign	Group Name	Admini	stration W	eek-day											
		1-7 1	2-7 1	3-7 1	4-7 1	5-7 1	6-7 1	7-7 1	8-7 1	9-7 1	10-7 1	11-7 1	12-7 1	13-7 1	14-7 1
BNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	n	n	٥
	25ppm	0	0	0	0	0	0	0	0	ñ	Ö	n	n	n	n
	100ppm	0	0	0	0	0	0	Ō	0	0	Ů.	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

PAGE: 42

Clinical sign	Group Name	Admini	stration W	eek-day											
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
BNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	٥
	25ppm	ŏ	0	ő	0	0	0	0	0	0	0	0	n	n	n
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
VIDEO IVII MINIS															
UBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ô	0

(HAN190)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

PAGE: 43

Clinical sign	Group Name	Admini	istration W	eek-day _										• • • • • • • • • • • • • • • • • • • •	
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
					<u> </u>			<u> </u>		<u> </u>		<u>, , , , , , , , , , , , , , , , , , , </u>		1	I
BNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0		0	0	0	n
	25ppm	0	0	0	0	0	0	Ō	0	Ö	Ö	ů	Ö	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
UBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ō
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

ALL A

SEX : MALE

PAGE: 44

Clinical sign	Group Name	Admini	istration W	eek-day _							· · · · · ·				
		43-7 1	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
				1	1	1	1	1		1	I		1	1	1
BNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	٥
	25ppm	0	0	0	0	0	Ö	Õ	Õ	0	0	0	n	n	n
	100ppm	0	0	0	0	0	0	0	Ö	Ô	0	0	n	n	0
	400ppm	0	0	0	0	0	0	0	0	0	Ö	0	ő	0	0
BNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	Ω
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	o o
	100ppm	0	0	0	0	0	0	0	0	. 0	0	0	0	0	ő
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ô	0

(HAN190)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

PAGE: 45

Clinical sign	Group Name	Admin	istration W	eek-day _											
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
BNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	٥	0	٥	0	0
	25ppm	0	0	0	0	Õ	Ö	0	0	0	0	n	n	0	0
	100ppm	0	0.	0	0	0	0	0	0	o o	0	0	n	n	0
	400ppm	0	0	0	0	0	0	0	0	0	Ö	0	Ö	0	0
JBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	Ô	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	Ô	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

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

SEX : MALE

PAGE: 46

Clinical sign	Group Name	Admini	stration W	eek-day _											
		71-7 1	72-7 1	73-7 1	74-7 1	75–7 1	76-7 1	77-7 1	78-7 1	79-7 1	80-7 1	81-7 1	82-7 1	83-7 1	84-7 1
BNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ô	Ô
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ô	ñ
	400ppm	0	0	0	0	0	0	0	0	0	0	Ō	0	1	1
BNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	n	٥
	25ppm	0	0	0	0	0	0	0	0	0	n	0	n	n	0
	100ppm	0	0	0	0	0	0	0	Ö	0	0	0	0	0	n
	400ppm	0	0	0	0	0	0	0	0	Õ	Ö	0	0	0	0

(HAN190)

ANIMAL : RAT F344/DuCrj

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

REPORT TYPE : A1 104

SEX : MALE

PAGE: 47

Clinical sign	Group Name	Admini	stration W	leek-day											
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
BNORMAL RESPIRA. SOUND	Company 1	^	^	•	•	•				_					
DNORMAL RESPIRA. SOUND	Control	0	0	0	0	. 0	0	0	0	0	0	0	0	0	0
	25ppm	U	0	Ü	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	1	0	0	0	0	0	0	0	0	0	0	0	0	0
UBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	n	ñ
	100ppm	0	0	0	0	0	0	0	0	0	Ô	0	Ô	ñ	1
	400ppm	0	0	0	0	0	0	0	0	Ů.	0	0	0	Ö	0

(HAN190)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : MALE

PAGE: 48

Clinical sign	Group Name	Admin	istration '	Week-dav				
		99-7	100-7	101-7	102-7	103-7	104-7	
		1	1	1	1	1	1	
ABNORMAL RESPIRA. SOUND	Control	0	0	0	0	0	0	
	25ppm	0	0	0	0	0	0	
	100ppm	0	0	0	0	0	0	
	400ppm	0	0	0	0	0	0	
SUBNORMAL TEMP	Control	0	0	0	0	0	0	
	25ppm	0	0	0	0	0	0	
	100ppm	0	0	0	0	0	0	
	400ppm	0	0	0	0	0	0	

(HAN190)

APPENDIX C 2

CLINICAL OBSERVATION: SUMMARY,

RAT: FEMALE

(2-YEAR STUDY)

STUDY NO. : 0417

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-day											
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
EATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Õ
DRIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ŏ
	100ppm	0	0	0	0	0	0	0	Ö	0	0	0	Ö	ő	0
	400ppm	0	0	0	0	0	0	0	Ö	Ö	0	0	0	0	0
ARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	Ō	Õ	0	0	0	0	0	0	0	ő	0	0
	100ppm	0	0	0	0	Ö	ů	0	Ö	0	0	0	0	0	0
•	400ppm	0	Ö	Ö	0	Ö	0	0	0	0	0	0	0	0	0
ASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	Õ	Ö	Ŏ	Ö	Ö	0	0	0	0	0			
	100ppm	0	Ö	ő	0	0	0	0	0	0	0		0	0	0
	400ppm	0	Ö	ő	0	0	0	0	0	0	0	0 0	0	0 0	0 0
OILED	Control	0	0	0	0	0	0	0	0	0	. 0	0	0	0	0
	25ppm	0	0	Ō	ŏ	Ö	0	0	0	0	0	0	0	0	0
	100ppm	0	0	Ö	ő	ů	0	0	Ö	0	0	0	•	-	
	400ppm	0	0	0	Ö	0	0	0	0	0	0	0	0 0	0 0	0 0
ILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	Ö	0	0	0	0	0	0	0	0	0	0	•	-	0
	100ppm	Ö	Ö	ō	0	0	0	0	-	-	_	-	0	0	0
	400ppm	0	0	0	0	0	0	0	0 0	0 0	0 0	0 0	0	0	0 0
ROLAPSE OF ANUS	Control	0	0	0	0	0	0	0	0	0	0	0	^	•	•
	25ppm	Ö	0	0	0	0	0	0	0			0	0	0	0
	100ppm	0	0	0	0	0	0	-		0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0 0	0 0	0 0	0 0	0	0	0	0
DILED PERI-GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	^		
	25ppm	0	0	0	0	0	0	0	0	-		0	0	0	0
	100ppm	0	0	0	0		-			0	0	0	0	0	0
	400ppm	0				0	0	0	0	0	0	0	0	0	0
	#UQQUM	U	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0417

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : FEMALE

linical sign	Group Name		istration V	∛eek-day _			"								
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
SATH	Control	0	0	0	0	0	0		•	•	•				
DI III	25ppm	0	0	0	0 0	0 0	0	0	0	0	0	0	0	0	0
	100ppm	0	0				0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	1	1
	400ppm	U	U	0	0	0	0	0	0	0	0	0	0	0	0
RIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	Ö	0	0	0	0	0	0	0	0
	100ppm	Ö	0	0	0	0	0	0	0	0	0	0	0	0	-
	400ppm	0	0	0	0	0	0	0	0	0	0				0
	100ppm	v	v	v	U	U	U	U	U	U	U	0	0	0	0
RALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ō
	100ppm	. 0	0	0	0	0	0	0	0	0	0	Ŏ	Ö	Ö	0
	400ppm	0	0	0	0	0	0	0	Ö	0	0	0	0	0	0
										-	•	•	•	·	v
STING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ILED	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	•
	25ppm	Ō	ŏ	Ö	0	0	0	0	0	0	0	0	0		0
	100ppm	Ö	ŏ	0	0	0	0	0		•			-	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	v	V	U	U	U	U	U	U	0	0	0	0	0	0
LOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	ő	0
	100ppm	0	0	0	0	0	0	0	Ŏ	Ö	Ö	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	Ö	ő	Ö	0	0	0
OLAPSE OF ANUS	A 1	^	^	^	•	_	_	_							
ODITION OF VIACO	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ILED PERI-GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	•	•
	25ppm	ő	1	0	0	0	0	0	0	0	0		-	0	0
	100ppm	0	0	0	0	0	0	_		•	•	0	0	0	0
	400ppm	0	0	0	0	0		0	0	0	0	0	0	0	0
	IIIQQOOF	U	U	U	U	U	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj ALL ANIMALS

REPORT TYPE : A1 104

STUDY NO. : 0417

SEX : FEMALE

Clinical sign	Group Name		istration W			<u> </u>					*,.				
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DATE!	0	^	^		۰	•	•	•							
EATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DRIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	. 0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	Ō	0	0	0	0	0	0	0	Ö	ō	ő
ASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	Ö	ō	Ö	Ö	Ö	0	0	0	0	0	0	0	0	0
	100ppm	Ö	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	Ö	0	Ö	0	0	0	0	0	0	0	0
OILED	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	Ö	Ŏ	Õ	Ö	0	ŏ	Ö	0	0	0	0	0	0	Ő
	100ppm	Ö	ő	0	Ö	0	0	0	0	0	0	0	0	0	
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0 0
ILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	Ö	ō	0	0	0	0	0	0	0	0	0	-	-	0
	100ppm	0	0	0	0	0	0	0	0	0		-	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0 0	0 0	0 0	0 0	0 0
ROLAPSE OF ANUS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	Ö	Ő	0	0	0	0	0	0	0	0	0	0	0	0 0
	100ppm	0	0	0	0	0	0	0	0						
	400ppm	0	0	0	0	0	0	0	0	0 0	0 0	0	0 0	0 0	0 0
DILED PERI-GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	_	_	0
	100ppm	0	0	0	0	0	0		-				0	0	0
	400ppm	0	0	0				0	0	0	0	0	0	0	0
	400ppm	U	U	U	0	0	0	0	0	0	0	0	0	0	0

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	istration W	eek-day _							-				
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
ЕАТН	C #- 1	^	^		٥	•	•	•				_			
EAIH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DRIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	1
	400ppm	0	0	0	0	0	0	0	0	0	0	ō	0	ō	ō
ASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ô
	100ppm	0	0	0	0	0	0	Ŏ	0	Ö	0	0	0	0	0
	400ppm	0	0	0	0	0	0	Ö	Ö	0	0	0	0	0	0
OILED	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	ō	Õ	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	Ö	Ö	Ö	0	0	0	0	0	0	0		•
	400ppm	0	0	Ö	0	0	0	0	0	0	0	0	0	0 0	0 0
ILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	
	25ppm	Ö	0	0	Ő	0	0	0	0	0	0	0	0	-	0
	100ppm	0	0	0	0	0	0	0	0	0		-	-	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0 0	0 0	0	0 0
ROLAPSE OF ANUS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
•	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	Ů	0	0	0	0	0						0	0
	400ppm	0	0	0	0	0	0	0	0 0						
OILED PERI-GENITALIA	Control	0	0	0	0	0	1	1	1	0	0	٥	0	0	•
	25ppm	0	0	0	0	0	0				-	0	0	0	0
	23ppm 100ppm	0	0					0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	U	υ	0	0	0	0	0	0	0	. 0	0	0	0	1

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

STUDY NO. : 0417

SEX : FEMALE

Clinical sign	Group Name		istration W					·						·	
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
ЕАТН	Control	0	0	0	0	0		0	0	0	0	0	0		0
LJ1111	25ppm	1	1	1	1	1	1	1	1		0 1	0		2	2
	23ppm 100ppm	1	1			1		-		1	-	1	1	1	1
	400ppm	1	1	1 1	1 1	1	1 1	1 1	1 1	1 1	1 1	1	1 1	1	1 1
	10 Oppm	•	•	1	*	1	1	1	1	1	1	1	1	1	1
DRIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	Ö	Ŏ	0	Ö	0	0	Ö	0	0	0	0	0	0	0
	100ppm	1	1	1	1	0	0	0	0	0	0	0	0	0	
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 0 bhu	v	V	V	v	U	v	U	U	U	υ	U	U	U	U
STING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DILED	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	Ō	ŏ	Ö	0	0	0	0	0	0	0	0	0	0	0
	100ppm	Ŏ	Ö	0	0	0	0	0	0	0	0	0	-	-	
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0 0	0	0
	IOO ppm	V	V	U	U	U	U	U	U	U	U	U	U	U	0
ILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ROLAPSE OF ANUS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	Ö	Õ	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	Ŏ	0	0	0	0	0	0	0	0	0	
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OTI DD DDD gmrau v						-	-	-		ŭ	ŭ	v	v	v	v
ILED PERI-GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	1	1	1	1	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

STUDY NO. : 0417

SEX : FEMALE

Clinical sign	Group Name	Admin:	istration W	leek-day											
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		1	1	1	1	1	1	1 .	1	1	1	1	1	1	1
EATH	Control	3	3	3	3	3	3	3	3	3	3	4	6	6	6
	25ppm	1	1	1	1	1	1	1	1	1	1	1	1	2	2
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400ppm	1	1	1	1	1	1	1	2	2	2	2	2	2	2
DRIBUND SACRIFICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400ppm	0	0	1	1	1	1	1	1	2	2	3	3	4	4
ARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0 -	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ô	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	ō	ō	Ö
ASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	100ppm	0	0	0	0	0	0	ō	ō	ō	Õ	0	Ô	0	0
	400ppm	0	0	0	0	0	0	0	ō	0	Ō	0	ő	Ö	ő
OILED	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	Ō	0	0	0	0
	400ppm	0	0	0	ō	0	0	0	ő	0	0	0	0	0	0
ILOERECTION	Control	0	0	0	0	0	0	0	0	1	1	0	0	0	0
	25ppm	0	0	0	0	0	0	0	Õ	Ô	0	0	0	0	0
	100ppm	0	0	Ö	Ö	ő	Ö	0	Ô	0	0	0	0	0	0
	400ppm	0	0	0	Ö	ŏ	0	ő	Ö	0	0	0	0	0	0
ROLAPSE OF ANUS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	Ō	Ö	Ö	0	0	0	Ö	0	0	0
	100ppm	0	0	0	0	0	0	0	Ŏ	Ö	Ő	Ŏ	Ô	0	0
	400ppm	0	Ö	o	Ö	0	0	0	0	0	0	0	0	1	1
DILED PERI-GENITALIA	Control	0	0	0	0	0	0	1	1	1	1	0	0	0	0
	25ppm	0	0	Ö	Ö	Õ	0	0	0	0	0	0	0	0	0
	100ppm	Ö	ō	Ö	Ö	0	0	0	0	0	0	0	0	0	1
	400ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	
	200pm	v	v	v	v	U	v	v	U	U	1	U	U	U	1

ANIMAL : RAT F344/DuCrj ALL ANIMALS

REPORT TYPE : A1 104

STUDY NO. : 0417

SEX : FEMALE

Clinical sign	Group Name		istration V												
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		1	1	1	1	1.	1	1	1	1	1	1	1	1	1
EATH	0 1			•		•									
CAIN	Control	6	6	6	6	6	6	6	6	6	6	6	6	7	7
	25ppm	2	2	2	3	3	3	3	3	4	4	4	4	4	4
	100ppm	1	1	1	1	1	1	1	2	2	2	2	. 2	2	2
	400ppm	2	2	2	2	2	2	2	2	2	2	3	4	4	5
DRIBUND SACRIFICE	Control	0	1	1	1	2	2	2	2	2	2	3	3	3	3
	25ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
	100ppm	1	2	2	3	3	3	3	3	3	3	3	3	3	3
	400ppm	4	5	5	5	6	6	7	8	10	10	11	12	12	12
ARALYTIC GAIT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	Ō	0	Ö	Ö	0	Ö	0	0	0	0	0
	100ppm	0	0	Õ	0	Ö	Ö	Ô	0	0	0	0	0	0	
	400ppm	0	0	0	0	0	0	0	0	0	0	0			0
	±00ppm	v	V	U	U	U	U	U	U	U	U	U	0	0	0
ASTING	Control	1	1	1	1	0	0	0	0	0	2	1	1	1	1
	25ppm	1	1	1	1	1	2	1	1	1	1	1	1	1	1
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	1	0	0	0	0	0	0	2	1
DILED	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	Ô	0	Ō	0	Ö
	400ppm	0	0	0	0	0	0	0	0	0	0	0	ŏ	Ö	0
ILOERECTION	Control	0	0	0	1	0	0	0	0	0	1	0	0	0	0
	25ppm	0	Ŏ	Ŏ	Ô	0	0	0	0	0	0	0	0	0	0
	100ppm	Ŏ	Ö	0	0	0	0	0	0	0	0	-	-	-	
	400ppm	0	ő	0	0	0	0	0	0	0	0	0	0 0	0 0	0 0
ROLAPSE OF ANUS	Control	0	0	0	0	0	0	0	0	0	0	^	^	•	•
	25ppm	0	0	0	0	0	0	0		-		0	0	0	0
	100ppm	0	0	0	0				0	0	0	0	0	0	0
		2				0	0	0	0	0	0	0	0	0	0
	400ppm	4	2	0	0	0	0	0	0	0	1	1	1	0	0
DILED PERI-GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	1	1	1	0	0	0	1	0	0	0	Ö	Ö	Ŏ	ŏ
	400ppm	1	0	0	0	0	0	1	2	0	0	0	0	Ô	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

SEX : FEMALE

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

Clinical sign	Group Name	Admin	istration	Week-day _				_
	-	99-7	100-7	101-7	102-7	103-7	104-7	
		1	1	1	1	1	1	
								_
DD 4 WY		_	_					
DEATH	Control	7	7	7	7	7	7	
	25ppm	4	4	4	4	4	4	
	100ppm	2	2	3	3	4	4	
	400ppm	6	8	9	9	9	9	
MORIBUND SACRIFICE	Control	4	1	1	E	-	-	
MONIDOND SHOKIFIED	25ppm		4	4	5	5	5	
	25ppm 100ppm	1 3	1	1	1	1	1	
			4	4	4	5	7	
	400ppm	12	12	12	13	14	15	
PARALYTIC GAIT	Control	0	0	0	0	0	0	
	25ppm	0	0	0	0	0	0	
	100ppm	0	0	0	0	0	0	
	400ppm	0	0	0	. 0	0	0	
	vpm	-	·	•	•	•	v	
WASTING	Control	0	0	0	0	0	1	
	25ppm	1	0	0	0	0	ō	
	100ppm	1	1	1	1	2	0	
	400ppm	1	1	2	3	2	1	
				_	-	-	~	
SOILED	Control	0	0	0	0	0	0	
	25ppm	0	0	0	0	0	Ō	
	100ppm	1	0	0	0	0	0	
	400ppm	0	0	0	1	0	0	
PILOERECTION	Control	0	0	0	0	0	0	
	25ppm	0	0	0	0	0	0	
	100ppm	0	0	0	0	0	0	
	400ppm	0	0	0	0	0	0	
DDOLADOR OF ANTIC	a			_				
PROLAPSE OF ANUS	Control	0	0	0	0	0	0	
	25ppm	0	0	0	0	0	0	
	100ppm	0	0	0	0	0	0	
	400ppm	1	2	0	1	1	1	
SOILED PERI-GENITALIA	C1	0	^			•	•	
POTERN LEWI-GENTIAPIN	Control	0	0	0	0	0	0	
	25ppm	0	0	0	0	0	0	
	100ppm	0	0	0	1	1	0	
	400ppm	1	1	2	1	1	1	

ANIMAL : RAT F344/DuCrj ALI

REPORT TYPE : A1 104

STUDY NO. : 0417

SEX : FEMALE

DDA - FEMALE															PAGE: 8
Clinical sign	Group Name	Admini	stration W	eek-day											
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
BYE OPACITY	0	^			•		•	•	•	•					_
STE UPACITY	Control 25ppm	0 0	0	0 0	0	0 1	0	0 1	0	0 0	0	0	0	0	0
	100ppm	0	0	0	0	0	1	0	1 0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0 0	0 0	0 0
CATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MYDRIASIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL GROWTH OF TEETH	Control	0	0	0	0	0	0	0 -	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	0	0	0	0	. 0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0 -	0	0	0

STUDY NO. : 0417 CLINICAL OBSI ANIMAL : RAT F344/DuCrj ALL ANIMALS

REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	stration F	eek-day											
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
THE ODIOTEN	a	•													
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	100ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	1
	400ppm	0	1	1	1	1	1	1	1	1	1	1	1	1	1
MYDRIASIS	Control	0	0	1	1	1	1	1	1	1	1	1	1	1	1
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Õ
	100ppm	0	0	0	0	0	Ö	0	0	Ö	0	0	0	Ö	0
	400ppm	0	0	0	0	0	ō	ō	Ö	Ö	Ō	Ö	0	0	0
ABNORMAL GROWTH OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	Õ	Ö	0	0	0	0	0	Ö
	100ppm	0	0	0	0	Ō	0	0	Ö	0	Ö	0	0	0	0
	400ppm	0	0	0	0	ō	ő	ő	ő	0	0	0	0	0	0
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	Ö	0	0	0	0	0	0
	100ppm	0	0	Ö	ō	Ö	Ô	0	0	1	1	1	1	0	
	400ppm	0	0	0	0	0	ő	ő	0	0	0	0	0	0	0 0
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	Ö	Ö	0	Õ	0	0	0	0	0	0	0	0	0
	100ppm	Ö	Ö	Ö	0	0	0	0	0	0	0	0			
	400ppm	0	Ö	Ö	0	0	0	0	0	0	0	0	0 0	0 0	0 0
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	Ö	Ö	0	0	0	0	0	0	0	0	0		-	0
	100ppm	0	0	0	0	0	0	-		-		•	0	0	0
	400ppm	0	0	0	0	0		0	0	1	1	1	1	0	0
	₩qqoo r	v	U	U	U	U	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

STUDY NO. : 0417

SEX : FEMALE

Clinical sign	Group Name	Admin	istration W	eek-day											
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
	-	1	1	1	1	1	1	1	1	1	1	1	I	1	1
YE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400ppm	1	1	1	ĩ	ī	î	1	1	1	1	1	ì	1	1
YDRIASIS	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	25ppm	0	0	ō	ō	0	0	Ō	Ô	0	0	Ô	0	Ō	0
	100ppm	0	0	Ö	ŏ	Ö	0	0	o O	0	0	0	0	0	0
	400ppm	0	ů	0	0	0	0	0	0	0	0	0	0	0	0
NTERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	Ö	0	Ö	0	. 0	0	0	0	0	0	0	0	-	
	100ppm	Ö	0	0	0	0	0	0	0	0	0	•		0	0
	400ppm	0	0	0	0	,0	0	0	0	0	0	0 0	0 0	0 0	0 0
BNORMAL GROWTH OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	ő	Ö	0	0	0	0	0	0	0	0	Ö	
	100ppm	Ö	0	0	0	0	0	0	0	0	0	0			0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0 0	0 0	0 0
XTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	Ō	Ŏ	ŏ	0	0	0	0	0	0	0	-	-	
	100ppm	0	0	0	0	0	0	0	0		-	•	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0 0	0 0	0 0	0 0	0 0	0 0
NTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* *	25ppm	0	0	0	0	0	0	0	0	0	0	0	0		
	100ppm	0	0	0	0	0	0	0	0	0	0	0	-	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0 0	0 0	0
. Nose	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
-	25ppm	0	0	0	0	0	0	0				•		-	0
	100ppm	0	0	0	0			-	0	0	0	0	0	0	0
		0				0	0	0	0	0	0	0	0	0	0
	400ppm	U	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj ALL ANIMALS

REPORT TYPE : A1 104

STUDY NO. : 0417

SEX : FEMALE

Clinical sign	Group Name		istration W	leek-day											
		43-7	44 -7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
· · · · · · · · · · · · · · · · · · ·		1	1	1	1	1	1	1	1	1	1	1	1	1	1
YE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATARACT	Control	0	1	1	1	1	1	1	1	1	1	1	2	2	2
	25ppm	1	1	1	1	1	1	1	1	1	1	1	2	2	2
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
YDRIASIS	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NTERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL GROWTH OF TEETH	Control	0	0	0 .	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	. 0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
XTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	Ō	0	Ō	0
. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	. 0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	Ō	0	ō	ŏ	Ő	Ö	Ö	0
	400ppm	0	0	0	0	0	0	0	Ō	Ö	Ö	Õ	0	ŏ	0

ALL ANIMALS

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

STUDY NO. : 0417

SEX : FEMALE

Clinical sign	Group Name	Admin:	istration Y	Yeek-day _											
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
YE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	. 0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATARACT	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	25ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400ppm	1	1	. 1	1	1	1	1	1	1	1	1	1	1	1
YDRIASIS	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	25ppm	0	0	0	Ô	Ô	0	Ô	Ô	Ô	0	0	Ō	0	0
	100ppm	ō	ŏ	ŏ	ŏ	0	Ö	Ö	0	Ö	0	0	ů	Ö	0
	400ppm	0	ő	0	Ö	Ö	0	0	0	0	0	0	0	0	Ö
NTERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	ő	Ö	Ö	Ö	Ö	0	0	0	0	0	0	0	0	0
	100ppm	. 0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BNORMAL GROWTH OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	Ö	ŏ	ő	ŏ	0	0	Ö	0	0	0	0	ő	0	0
	100ppm	ŏ	0	Ö	Ŏ	0	Ŏ	Ŏ	0	0	0	0	0	0	0
	400ppm	0	0	0	Ö	0	0	0	0	0	0	0	0	0	1
XTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	Ö	Ö	0	0	0	0	0	0	0	0	0	0
	100ppm	1	1	1	1	2	2	2	2	2	2	2	2		
	400ppm	0	0	0	Ô	0	0	0	1	2	1	1	1	2 1	2 1
NTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	ŏ	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	ő	0	0	0	0	0	0	0	0	0	0	
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0 0
1. NOSE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	Ö	0	0	0	0	0	0	0	0	0	0	0		
	23ppm 100ppm	0	0	0	0	0	0	0	0	0				0	0
		0	0	0	0	0	0				0	0	0	0	0
	400ppm	U	U	U	U	U	U	0	0	0	0	0	0	0	0

ALL ANIMALS

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : FEMALE

STUDY NO. : 0417

SEA · FEMALE															PAGE :
Clinical sign	Group Name	Admin	istration V												
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
ND ODIGITAL		•													
YE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm 400ppm	0	0 0	0	0 0	0 0	0	0 0	0						
ATARACT	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	25ppm	2	2	2	3	3	3	3	3	3	3	3	3	3	4
	100ppm	1	1	1	1	1	2	2	2	2	2	2	2	2	2
	400ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
MYDRIASIS	Control	1	1	1	1	1	1	1	1	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NTERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL GROWTH OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	1	1	1	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	25ppm	0	0	1	1	1	1	1	1	1	1	1	1	1	1
	100ppm	2	2	2	2	2	2	2	2	2	3	3	3	3	4
	400ppm	1	1	1	2	2	2	2	2	2	2	3	4	6	6
NTERNAL MASS	Control	0	0	0	0	0	0	0	1	1	1	0	0	0	0
	25ppm	0 0	0 0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm 400ppm	0	0	0 0	0 0	0 0	0 0	0 0	0	0 1	0 1	0 0	0 0	0 0	0 0
M. NOSE	Control	0	0	0	0	0	0	0	0	0	0	٥	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm 100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-day											
	-	85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		1	1	1	1	1	1	1	1	1	1	.1	1	1	1
			.,								· · · · · · · · · · · · · · · · · · ·				
YE OPACITY	Control	0	0	1	1	1	1	1	1	1	1	1	1	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ATARACT	Control	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	25ppm	4	4	5	5	5	5	5	5	5	5	5	5	5	5
	100ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	
	400ppm	1	1	1	1		1								2
	mqqvof	F	i	1	1	1	1	1	1	1	1	1	1	1	1
YDRIASIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	ō	0
NTERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	25ppm	0	0	0	Ö	0	0	0	0	0	0	0	0	0	0
	100ppm	Ö	Ö	Ŏ	Ö	0	0	0	0	0	0	0	0	0	
	400ppm	Ö	0	Ö	0	0	0	0	0	0	0	0	0	0	0
BNORMAL GROWTH OF TEETH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	^
Dividual dividual of 199111	25ppm	0	0	0	0	0	0	0	0	0		-	-	0	0
		0	0					-	•		0	0	0	0	0
	100ppm			0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	1	1	1	1	1	1	0	0	0	0	0	0
XTERNAL MASS	Control	1	1	1	1	1	1	1	2	3	3	2	2	4	5
	25ppm	2	2	2	2	3	3	3	4	4	5	5	5	5	5
	100ppm	3	3	3	3	4	4	5	4	5	5	6	8	9	9
	400ppm	6	7	7	8	8	10	9	9	6	6	6	7	7	7
VTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	Ō	Ŏ	ŏ	Ö	0	0	Ů	0	0	0	0	0	0
	100ppm	1	1	1	0	0	0	0	0	0	•	•			
	400ppm	Ô	Ō	0	0	1	2	2	2	1	0 1	0 2	0 1	0 1	0
. NOSE	Con+ma1	0	0	0	0	0	0	•		•	•	•			
· HODE	Control		-	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0417 CLINICAL OBS ANIMAL : RAT F344/DuCrj ALL ANIMALS

REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admin	istration N	Week-day					
	oup	99-7	100-7	101-7	102-7	103-7	104-7		
		1	1	1	1	1	1		
						 		 	
YE OPACITY	Control	0	0	0	0	0	0		
	25ppm	0	0	0	0	0	0		
	100ppm	0	0	0	0	0	0		
	400ppm	0	0	0	0	0	0		
'ARACT	Control	2	2	2	2	2	2		
	25ppm	5	5	5	5	5	5		
	100ppm	2	2	2	2	2	2		
	400ppm	1	1	1	0	0	0		
RIASIS	Control	0	0	0	0	0	0		
	25ppm	0	0	0	0	0	0		
	100ppm	0	0	0	0	0			
		0					0		
	400ppm	U	0	0	0	0	0		
ERIOR CHAMBER OPACITY	Control	1	1	1	1	0	0		
	25ppm	0	0	0	0	0	0		
	100ppm	0	0	0	0	0	0		
	400ppm	0	0	0	0	0	0		
DRMAL GROWTH OF TEETH	Control	0	0	0	0	0	0		
	25ppm	Ö	0	0	0	0	0		
	100ppm	0	0	0		0			
		0	0	0	0 0	0	0		
	400ppm	U	U	U	U	U	0		
RNAL MASS	Control	5	6	6	7	7	8		
	25ppm	6	6	6	8	8	9		
	100ppm	9	9	9	9	9	9		
	400ppm	7	7	7	7	6	6		
RNAL MASS	Control	0	0	1	0	0	0		
	25ppm	0	ŏ	Ô	0	0	Ö		
	100ppm	Ö	0	0	0	1	1		
	400ppm	1	1	1	0	0	0		
		•	*	1	v	v	•		
NOSE	Control	1	1	1	1	1	1		
	25ppm	0	0	0	0	0	0		
	100ppm	0	0	0	0	0	ō		
	400ppm	0	0	0	0	0	ō		

STUDY NO. : 0417 ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-day											
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
.PERI-MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	ő	ŏ
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0 .	0	0
	25ppm	0	Ō	Ö	Ö	0	0	0	Ö	Ö	0	0	0	0	0
	100ppm	0	0	0	0	0	0	o O	0	Ŏ	0	0	Ö	0	0
	400ppm	0	0	0	0	0	Ö	Ö	Ö	Ö	0	0	0	0	0
BREAST	Control	0	0	0	0	0	0	0	0	0	0	0		•	
	25ppm	0	0	0	0	0	0	0	0			0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	ő	0	0	0	0	0	0	0	0	0 0	0	0 0	0 0
. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	^	•	•
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0			0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0 0	0 0	0	0	0	0 0
ANTERIOR. DORSUM	Control	0	0	0	0	0	^	^	•	•	•	•			
THITIMION. DONOCH	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm 100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0 0	0 0	0	0 0	0 0	0 0	0	0 0	0	0 0
POSTERIOR DORSUM	Control 1	0	0	0	0	0	^	^	•	•	_	· .	•		
I ODIEKTOR DORDOM	Control 25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				0	0	0	0	0	0	0	0	0	0	0	0
	100ppm 400ppm	. 0	0 0	0	0 0	0	0	0 0	0	0 0	0	0	0	0	0 0
GENITALIA		•	-		-		-	•				_			
GENTIALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0417 ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admini	istration W	eek-day											
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
I. PERI-MOUTH	Control	0	^	0	0	•	•	•	•	,					
. FERT-MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	•	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	Ō	0	Ö	Ö	Ö
	400ppm	0	0	0	0	0	0	0	0	0	0	Ō	0	0	0
. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	^
. I John	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0 0	0 0
	100ppm	0	0	0	0	0	0	0	0	0	0	0			
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	#00bfm	U	U	U	U	U	U	Ū	U	U	U	U	0	0	0
BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	Õ	Ō	Ō	0	0	0	Ö	0	0	0	0	0	ő
	100ppm	0	0	0	0	Ö	0	ŏ	0	0	0	0	0	0	ő
	400ppm	0	0	Ō	Ö	0	Ö	Ö	Ŏ	0	0	0	0	0	0
ANTERIOR, DORSUM	Control	0	0	0	0	•	^	0		•		•		_	_
ANTENTON: DONOUM	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm 100ppm	0	0	0	0	0	0		0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0 0	0 0	0 0	0 0	0 0	0 0	0	0	0
	#00bbin	V	U	U	U	U	V	U	U	U	U	U	0	0	0
POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	Õ	Õ	Ö	0	0	0	0	0	0	0	0	0	0
	100ppm	0	Ô	Ŏ	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	Ŏ	0	0	0	0	0	0	0	0	0	0	0	0
	2000	•	•	•	Ū	v	v	U	v	v	U	U	U	U	U

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name		istration N												
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
PERI-MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	Ō	Ö
	400ppm	0	0	0	0	0	0	Ō	0	0	Ō	Ő	0	Ö	0
. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	0	Ö
BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	ő
	100ppm	0	0	0	0	0	0	Ŏ	ō	Ŏ	Ö	0	0	Ö	0
	400ppm	0	0	0	0	0	0	0	0	0	0	Ö	ő	0	0
. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ö	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. ANTERIOR. DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ö	Ŏ
	100ppm	0	0	0	0	0	0	0	Ŏ	ŏ	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	Ö	0	Ö	ő
POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	Ō	0	0	0	Ö	Ö	0
	100ppm	0	0	0	0	0	0	0	Ŏ	Ŏ	Ö	0	0	0	0
	400ppm	0	0	Ö	0	0	Ö	Ö	0	ő	0	0	0	0	0
GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	Ŏ	Õ	0	0	0	0	0
	100ppm	Ō	Ŏ	Ŏ	0	Ö	0	0	0	0	0	0	0	0	0
	400ppm	ō	0	Ö	Ö	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0417

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name	Admin	istration Y	Yeek-day _											
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
	· · · · · · · · · · · · · · · · · · ·	1	1	1	1	1	1	1	1	1	1	1	1	1	1
PERI-MOUTH	Control	0	0	0	0	0	^	0	٥	•	٥	•	•	•	
TERT MOUTH	25ppm	0	0	0	0 0	0 0	0	0	0	0	0	0	0	0	0
	25ppm 100ppm	0	0							0	0	0	0	0	0
	400ppm	0	0	0	0 0	0 0	0	0 0	0	0	1 0	1 0	1 0	1 0	1 0
	Tooppii	v	V	V	U	O	V	U	U	U	U	U	U	U	U
MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	ő	Ö	0	0	0	0	0	0	0	0	0	0		
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	тоорры	v	v	V	U	O	U	U	U	V	U	U	U	U	0
BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	ő	Ö	0	0	0	0	0	0	0	0	0	0		
	100ppm	ő	ő	0	0	0	0	0	-					0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	тооррш	U	v	U	U	U	Ü	U	0	0	0	0	0	0	0
ANTERIOR. DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ö	0
	400ppm	0	0	0	0	0	0	0	0	0	Ō	0	Ö	Ö	Ö
POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	^	^	^	^	^
PORDOM	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0			0	0	0	0	0
	400ppm	0	0	0	0	0			0	0	0	0	0	0	0
	4 00ppm	U	U	U	U	U	0	0	0	0	0	0	0	0	0
GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	0	Ö
	100ppm	0	0	0	0	0	0	0	0	ō	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	Ö	0	0	0	0	0	0

ALL ANIMALS

STUDY NO. : 0417 ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

SEX : FEMALE

014-4-1-4-	G 31														
Clinical sign	Group Name		istration V		CA 7	C1 5	CO 17	20. 7	0.1.7	25.7	00.7				····
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70–7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
, PD2 100 mg															
M. PERI-MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400ppm	0	0	0	0	0	0	0	0	1	0	0	0	0	0
M. MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	. 0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	ŏ	Ö
	400ppm	0	0	0	0	0	0	0	0	Ö	Ö	Õ	Ö	0	0
M. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	Ö	0	0	0	0	0	0	0	0	0	0
	100ppm	ŏ	0	0	0	1	1	1	1	1	1	1	1		
	400ppm	ō	Ö	Ő	0	0	0	0	0	0	0	0	0	1 0	1 0
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	ō	ŏ	0	0	Ö	0	0	0	0	0	0	0	0	0
	100ppm	Ö	Ŏ	Ö	0	0	0	0	0	-	-	-		-	-
	400ppm	o	0	0	0	0	0	0	1	0 1	0 1	0 1	0 1	0 1	0 1
M. ANTERIOR. DORSUM	Control	0	. 0	0	0	0	0	0	0	0	0	0	0	^	0
	25ppm	Ö	0	Ö	0	0	0	0		-	-	-	-	0	0
	100ppm	Ö	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	ő	0	0	0	0	0	0	0 0	0	0 0	0 0	0 0	0 0	0 0
1. POSTERIOR DORSUM	Control	0	0	0	0	0	0	٥	0	^	^	•	•	•	•
	25ppm	0	0	0	0	0	0	0	0	0 0	0	0	0	0	0
	100ppm	Ô	0	0	0	0					0	0	0	0	0
	400ppm	0	0	0	0	0	0 0	0							
M. GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0					0	0	0	0
	25ppm 100ppm	0	0	0	0	0		0	0	0	0	0	0	0	0
	400ppm	0	0	0	0		0	0	0	0 .	0	0	0	0	. 0
	400ppm	U	U	U	U	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0417

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

SEX : FEMALE

Clinical sign	Group Name		istration W												
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
I. PERI-MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ррт	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. MANDIBULAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	Ô	0	Ō	0	Ö	Ö
	100ppm	Ö	Ö	0	0	Ö	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
I MECV		•	•	•											
I. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	Ö	0	Ö	0	0	Ô	0	0	0	0	0			
	100ppm	1	1	1		-							0	0	0
		0	0	0	1	1	1	1	1	1	1	1	1	1	1
	400ppm	U	U	U	0	0	0	0	0	0	0	0	0	1	1
. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	25ppm	0	0	1	1	1	1	1	1	1	1	1	1	1	1
	100ppm	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	400ppm	1	1	1	1	1	1	1	1	1	1	ī	1	2	2
I. ANTERIOR. DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	Ö	0	0	0	0	0	0	0	0	0	-	-	-	0
	100ppm	0	0	0	0	0	0		-			0	0	0	0
	400ppm	0	0	0	1	1	1	0 1							
L POSTERIOR DORSUM	0	•	•	•	•	•			_		_	_			
MUCAUM MULMATCO 1.	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
. GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	Ö	0	0	0	0 -	0	0	0	0	0	0	0
	100ppm	ő	0	Ó	0	0	0	0	0		_		-	-	-
	400ppm	0	0	0	0	0	0			0	0	0	0	0	1
	400ppm	v	U	U	U	U	U	0	0	0	0	1	2	2	2

ANIMAL : RAT F344/DuCrj ALL ANIMALS

REPORT TYPE : A1 104

STUDY NO. : 0417

SEX : FEMALE

		85-7	86-7	87-7	00.7	00.5	~ ~ ~	~ -	00.7	00 #		05.5	00.7	07 7	
				01.1	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
222 × 1441															
.PERI-MOUTH	Control	0	0	0	0	0	0	0	0	1	1	0	0	0	0
	25ppm	0	0	0	0	0	0	. 0	0	0	0	0	0	0	0
	100ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	400ppm	0	0	0	0	0	1	1	1	0	0	0	0	0	0
. MANDIBULAR	Control	0	0	0	0	. 0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	1	1	1	0	0	0	0	0	0	0	Õ
. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	Ō	0	Õ	Ö	Ö	Ö	Ö	0	0	0	0	0	0	0
	100ppm	Ö	0	ő	Ő	0	0	0	0	1	1	1	1		1
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	1 0	
	#00blit	V	V	v	v	v	U	v	U	U	U	U	U	U	0
. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	25ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	100ppm	1	1	1	1	1	1	2	1	1	1	2	2	2	2
	400ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
. ABDOMEN	Control	1	1	1	1	1	1	1	2	2	2	2	2	2	2
	25ppm	1	1	1	1	1	1	1	2	2	2	2	2	2	2
	100ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	400ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
. ANTERIOR. DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	25ppm	0	0	0	0	0 .	0	0	0	0	0	0	-	1 0	1
	100ppm	0	0	0	0	0 .	0	0	0	0	0		0		0
	400ppm	1	1	1	1	1	1	1	1			0	0	0	0
	400phii	1	1	1	1	1	1	ı	1	1	1	1	1	1	1
POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
.GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	25ppm	Ö	0	Ö	0	1	1	1	1	1	2	2	2	2	2
	100ppm	1	1	1	1	2	2	2	2	2					
	400ppm	2	3	3	3	3	4	4	4	2	2 2	2 2	3	4 3	4 3

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admin	istration '	Week-day _						
	-	99-7	100-7	101-7	102-7	103-7	104-7		 	
		1	1	1	1	1	1			
	, , , , , , , , , , , , , , , , , , ,								 	
M. PERI-MOUTH	Control	0	0	0	0	0	0			
	25ppm	0	0	0	0	0	0			
	100ppm	1	1	1	1	0	0			
	400ppm	0	0	0	0	0	0			
A. MANDIBULAR	Control	0	0	0	0	0	0	•		
	25ppm	Ō	ō	0	Ö	Ö	0			
	100ppm	Ö	ŏ	0	Ö	0	ŏ			
	400ppm	Ŏ	0	0	0	0	0			
	adddor.	v	v	U	U	U	U			
M. NECK	Control	0	0	0	0	0	0			
	25ppm	0	0	0	0	0	0			
	100ppm	1	1	1	1	1	1			
	400ppm	0	1	1	1	0	. 0			
			-	-	•	·	· ·			
M. BREAST	Control	1	1	1	1	1	1			
	25ppm	1	1	1	2	2	4			
	100ppm	2	2	2	2	2	2			
		1	1	1						
	400ppm	1	1	1	1	1	1			
A. ABDOMEN	Control	1	1	1	1	1	1			
	25ppm	3	3	3	3	3	3			
	100ppm	1	1	1	1	2	2			
	400ppm	2	2	2						
	mqqoo r	۵	4	4	2	2	. 2			
M. ANTERIOR. DORSUM	Control	1	1	1	1	1	1			
	25ppm	0	ō	0	0	Õ	ō			
	100ppm	Ö	o	0	0	0	0			
	400ppm	1	1	1	1	1	1			
	100ppm	^	•	-	*	-	1			
M. POSTERIOR DORSUM	Control	0	0	0	0	0	1			
	25ppm	Ö	ő	Ö	0	0	0			
	100ppm	Ö	ő	0	Ö	0	0			
	400ppm	0	0	0	0					
	400ppm	U	U	U	U	0	0			
M. GENITALIA	Control	1	2	2	3	3	4			
	25ppm	2	2	2	3	3	3			
	100ppm	4	4	4	4	4	4			e e
	400ppm	3	2	2	2	2	2			
	mddoo r	ð	4	۷	4	4	۷			

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

STUDY NO. : 0417

SEX : FEMALE

linical sign	Group Name	Admini	stration We	eek-day											
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7	14-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
UNDICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
USTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
REGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	ō
	400ppm	0	0	0	0	0	0	0	0	0	Ō	0	ō	0	0
SPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	Ō	Ö	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	Ŏ	Ö	ő
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	Ō	Ō	Ö	0	0	Ö	Ö	0
	100ppm	0	0	0	0	0	0	0	0	0	0	Ö	0	Ö	0
	400ppm	0	0	0	0	0	0	0	0	0	Ō	Õ	Ô	Ö	ő

CLINICAL OBSERVATION (SUMMARY)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

: RAT F344/DuCrj ALL ANIMALS

SEX : FEMALE

linical sign			stration W	con ua,											
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
UNDICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	Ō	0	Ö	Ö	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	Ö	n
	100ppm	0	0	0	0	0	0	0	ŏ	0	0	0	Ö	Ö	Ő
	400ppm	0	0	0	0	0	0	0	0	0	0	Ō	0	Ö	0
REGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	Ō	Ō	0	Ö	0	0	ő	Õ	0	0	0	0	0	0
	100ppm	0	0	0	Ō	0	0	0	ŏ	Ö	0	0	Ô	0	0
	400ppm	0	Ö	o o	0	ő	Ö	0	ő	0	0	0	0	0	0
SPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	ŏ	Ŏ	Ô	Ö	ő	0	0	0	0	0	0
	400ppm	0	0	0	0	0	Õ	Ö	ŏ	0	0	0	0	0	0
EP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	Ō	0	Ö	Ŏ	Ö	0	Ö	Ô	0	0	0	0
	100ppm	0	0	Ō	Ō	0	0	0	ŏ	0	0	0	0	0	0
	400ppm	0	Õ	0	ő	0	0	0	0	0	0	0	0	0	0

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

STUDY NO. : 0417

SEX : FEMALE

Clinical sign	Group Name	Admini	stration \	eek-day											
		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CRUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ö	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ö	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	Ō	0	0	Õ	0	0
	100ppm	0	0	0	0	0	0	0	Ō	Ö	Ŏ	0	0	0	ő
	400ppm	0	0	0	0	0	0	Ō	Ö	Ö	0	0	Ö	Ö	0
EEP BREATHING	Control	0	0	0	0	0	0	0	0	. 0	0	0	0	0	0
	25ppm	0	Ō	Ō	Õ	Ö	Ö	0	Ö	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	Ö	Ö	Õ	Ö	0	0	0
	400ppm	0	0	0	0	0	Ô	0	0	0	ů	0	0	0	o o

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 104

SEX : FEMALE

linical sign	Group Name		istration Y												
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
MIA	Control	0	0	0	٥	0	0	0	0	^	^	^		٥	•
MIN	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	Ö	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	Ö	o o	0	Ö	Ö	0	0	0	0	0	0	0
NDICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ISTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
P BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

CLINICAL OBSERVATION (SUMMARY)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-dav											
	-	57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
,						·									-
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JAUNDICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	ō	0	ŏ	Ō	Ö	Ö	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CRUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	-	0	-		-
	400ppm	0	0	0	0	0	0	0	0		0	-	0	0	0
	400phii	U	V	U	U	U	U	U	U	0	0	0	0	0	0
HEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	Ö	Ö	Ö	0	0.	0	0	0	0	0	0	0	0
	100ppm	0	Ö	Ö	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	^	•	•	•	•
DAMINING	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm 100ppm	0	0	0	0				0	0	0	0	0	0	0
	400ppm	0	0	0	0	0 0	0 0	0	0	0	0	0	0	0	0
	#400bbm	U	U	U	U	U	U	0	0	0	0	0	0	0	0

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

SEX : FEMALE

inical sign	Group Name		istration 🎙	leek-day											
		71-7	72-7	73-7	74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
NEMIA	0 . 1	•	•	•											
NEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm		0	0	0	0	0	0	0	0	0	0	0	0	1
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	U	1	0	0	0	0	0	0	0	0	0	0	. 0	0
UNDICE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	Ö	0	0
	100ppm	0	0	0	0	0	0	0	Ō	ŏ	Ö	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	1	0	0
RUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	Ō	Ö	0	0	0	0	0	0	Ö	0	0
	100ppm	0	0	0	0	0	0	0	0	Ö	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	ő	ő	ő
MORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	Ö	0	0	0	0	1	0	0
	100ppm	0	Ö	0	ŏ	Ö	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	Ō	0	1	1	Ö	0	ő	0	0
REGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	^
	25ppm	ō	Ŏ	Õ	Ö	0	0	0	0	0	0	0	0	0	0
	100ppm	0	Ö	0	ő	0	0	0	0	0	0	0	0	0	0 0
	400ppm	0	0	0	Ö	0	0	0	0	0	0	0	0	0	0
SPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	٥
	25ppm	0	Ö	Ö	0	0	0	0	0	0	0	0	0	0	0
	100ppm	ō	Ŏ	0	ő	0	0	0	0	0	0	0	0	•	0
	400ppm	0	0	ō	0	0	o	0	0	0	0	0	0	0 0	0 0
EP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	٥	0	•
	25ppm	Ö	ő	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	ŏ	Ö	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	Ö	Ö	0	0	0	0	0	0	0	0	0 0	0 0

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admin	istration W	Yeek-day _											
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
ANEMIA	Control	0	0	0	0	0	0	0	0	1	1	1	1	1	1
	25ppm	1	1	0	0	0	2	1	1	1	1	1	1	1	1
	100ppm	0	0	1	0	0	0	1	1	0	0	0	1	1	1
	400ppm	0	0	0	0	0	0	1	1	1	1	1	0	0	0
JAUNDICE	Control	0	0	0	0	0	0	0 .	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	2	2	1	1	1	0	0	0
CRUSTA	Control	0	0	0	0	0	0	0	0	0	0	1	1	1	2
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
HEMORRHAGE	Control	. 0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
•	100ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	1	1	0	0	0	0	0	0	0	0	0	1	1
	400ppm	0	0	0	0	0	1	0	0	0	0	0	0	1	1
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	0	Ö	ő
	100ppm	0	0	0	0	0	Ö	Ö	Ö	Ŏ	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	ō	Ö
DEEP BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	Ō	0	Ŏ	Ö	Ö	0	ő	0	0	0	0
	100ppm	0	0	0	Õ	0	Ö	Ö	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	Ö	Ö	0	0	0	0	0	0	0

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

SEX : FEMALE

Clinical sign	Group Name	Admin	istration '	Week-day			
	-	99-7	100-7	101-7	102-7	103-7	104-7
		1	1	1	1	1	1
ANEMIA	Cantanal	٥	•	•	^	•	
AINEMIA	Control	0	0	1	0	0	1
	25ppm	1	1	1	1	1	1
	100ppm	3	1	0	0	1	1
	400ppm	0	1	1	1	0	0
JAUNDICE	Control	0	0	0	0	0	1
January 2 Cld	25ppm	0	0	0	0	0	1
	29pm 100ppm	0	0	0	0		0
	400ppm	0	0	0	0	0	0
	#AAAAM	U	U	U	U	0	0
CRUSTA	Control	2	2	2	2	2	2
	25ppm	0	0	0	Ö	0	0
	100ppm	0	0	Ö	Ŏ	ő	0
	400ppm	1	0	0	Ö	0	0
					-	-	•
HEMORRHAGE	Control	0	0	0	0	0	1
	25ppm	0	0	0	0	0	0
	100ppm	1	0	0	0	0	Ō
	400ppm	0	0	0	0	0	0
TDDD CLARK TO THE CONTROL OF THE CON							
IRREGULAR BREATHING	Control	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0
	400ppm	1	1	1	0	0	0
RESPIRATORY SOUND ABNOR	0	•				_	_
MONGA UNION INOTANTICAN	Control	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0
	400ppm	0	1	1	1	1	0
DEEP BREATHING	Control	0	0	٥	0	^	٥
	25ppm	0	0	0 0	0	0	0
	23ppm 100ppm	1			0	0	0
	400ppm	1	1 1	1 1	1	1	0
	mqqvo r	1	1	1	1	1	0

APPENDIX D 1

BODY WEIGHT CHANGES: SUMMARY,

RAT: MALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

UNIT : g

REPORT TYPE : A1 104

SEX : MALE

BODY WEIGHT CHANGES ALL ANIMALS (SUMMARY)

oup Name	Adminis	stration	week-day											
	0-0		1-7		2-7		3-7		4-7		5-7		6-7	
Control	112±	4	142±	7	176±	10	202±	12	227±	12	245±	14	260±	15
25ppm	112±	4	141±	7	176±	10	204±	10	228土	11	246±	12	262±	13
100ppm	112±	5	140±	7	175±	9	203±	10	227±	11	246±	12	262±	12
400ppm	112±	4	131±	6**	158±	7**	179±	7 * *	195±	8**	209±	8**	221±	8**
Significant differen	ce; *:P≦0.	05	**: P ≦ 0.0	1			Test of Du	innett						

(HAN260)

BAIS 4

ANIMAL : RAT F344/DuCrj

UNIT : g
REPORT TYPE : A1 104

SEX : MALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

PAGE: 2

roup Name	Admini	istration	week-day											
	7-7		8-7		9-7		10-7		11-7		12-7		13-7	
Control	273±	16	284±	17	294±	18	301±	18	309±	18	315±	19	322±	21
25ppm	275±	14	286±	15	296±	15	306±	16	312±	16	318±	17	325±	18
100ррш		13	288±	14	299±	15	307±	15	314±	17	322±	17	328±	18
400ppm	230±	8**	239±	9**	251±	9 * *	257±	9**	260±	9**	266±	9**	272±	10**

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

Test of Dunnett

(HAN260)

BAIS 4

ANIMAL : RAT F344/DuCrj

UNIT : g

REPORT TYPE : A1 104

SEX : MALE

BODY WEIGHT CHANGES ALL ANIMALS (SUMMARY)

up Name	Administra	tion week-day							•••				
	14-7	18-7		22-7		26-7		30-7		34-7		38-7	
Control	327± 21	344±	23	359±	25	372±	26	377±	27	389±	30	397±	29
25ppm	331± 17	348±	18	365±	19	376±	20	382±	20	395±	22	401±	22
100ppm	335± 18	352±	20	369±	22	381±	25	390±	18	401±	19	407±	23
400ppm	277± 10*	* 292±	10**	305±	11**	320±	12**	327±	12**	342±	14**	351±	13**
Significant difference	e; *: P ≤ 0.05	**: P ≤ 0.0)1			Test of D	ınnett			<u>.</u>			

(HAN260)

BAIS 4

ANIMAL : RAT F344/DuCrj

UNIT : g REPORT TYPE : A1 104

SEX : MALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

42-7		46-7		50-7		54-7		58-7		62-7	,	66-7	
403±	31	412±	32	415±	33	414±	34	421±	34	425±	33	426±	33
407±	22	418±	23	421±	23	423±	23	427±	22	429±	24	432±	24
415±	21	422±	21	425±	21	425±	21	431±	23	433±	23	435±	23
349±	18**	339±	14**	345±	15**	347±	15≉≉	351±	17**	355±	18**	351±	16**
	407± 415±	407± 22 415± 21	407± 22 418± 415± 21 422±	407± 22 418± 23 415± 21 422± 21	$407\pm$ 22 $418\pm$ 23 $421\pm$ $415\pm$ 21 $422\pm$ 21 $425\pm$	$407\pm$ 22 $418\pm$ 23 $421\pm$ 23 $415\pm$ 21 $422\pm$ 21 $425\pm$ 21	407± 22 418± 23 421± 23 423± 415± 21 422± 21 425± 21 425±	$407\pm$ 22 $418\pm$ 23 $421\pm$ 23 $423\pm$ 23 $415\pm$ 21 $422\pm$ 21 $425\pm$ 21 $425\pm$ 21	407± 22 418± 23 421± 23 423± 23 427± 415± 21 422± 21 425± 21 425± 21 431±	$407\pm$ 22 $418\pm$ 23 $421\pm$ 23 $423\pm$ 23 $427\pm$ 22 $415\pm$ 21 $422\pm$ 21 $425\pm$ 21 $425\pm$ 21 $431\pm$ 23	$407\pm$ 22 $418\pm$ 23 $421\pm$ 23 $423\pm$ 23 $427\pm$ 22 $429\pm$ $415\pm$ 21 $422\pm$ 21 $425\pm$ 21 $425\pm$ 21 $431\pm$ 23 $433\pm$	$407\pm$ 22 $418\pm$ 23 $421\pm$ 23 $423\pm$ 23 $427\pm$ 22 $429\pm$ 24 $415\pm$ 21 $422\pm$ 21 $425\pm$ 21 $425\pm$ 21 $425\pm$ 21 $431\pm$ 23 $433\pm$ 23	$407\pm$ 22 $418\pm$ 23 $421\pm$ 23 $423\pm$ 23 $423\pm$ 23 $427\pm$ 22 $429\pm$ 24 $432\pm$ 415 \pm 21 $422\pm$ 21 $425\pm$ 21 $425\pm$ 21 $425\pm$ 21 $431\pm$ 23 $433\pm$ 23 $433\pm$ 23 $435\pm$

(HAN260)

BAIS 4

ANIMAL : RAT F344/DuCrj

UNIT : g
REPORT TYPE : A1 104

SEX : MALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

PAGE: 5

roup Name	Administration	week-day					
	70-7	74-7	78-7	82-7	86-7	90-7	94-7
Control	428± 34	424± 38	427± 41	424± 43	427± 30	429± 32	425± 32
25ppm	434± 25	432± 30	435± 29	436± 38	428± 30	430± 23	424± 26
100ppm	439± 22	436± 23	436± 28	434± 36	435± 21	435± 22	431± 24
400ppm	352± 16**	349± 16**	347± 17**	339± 20≉≉	338± 17**	334± 17**	329± 18**

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

Test of Dunnett

(HAN260)

ANIMAL : RAT F344/DuCrj

UNIT : g

REPORT TYPE : A1 104

SEX : MALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

Name	Administration	week-day		
	98-7	102-7	104-7	
Control	420± 31	414± 28	408± 31	
25ррш	416± 27	412± 29	405± 31	
100ррш	414± 49	420± 35	412± 44	
400ppm	324± 19**	313± 26**	305± 28**	
ignificant differenc	e; *:P≦0.05 *	*: P ≤ 0.01	Test of Dunnett	

(HAN260)

APPENDIX D 2

BODY WEIGHT CHANGES: SUMMARY,

RAT: FEMALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

UNIT : g REPORT TYPE : A1 104

SEX: FEMALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

PAGE: 7

p Name	Administra	tion week-day											
	0-0	1-7		2-7		3-7		4-7		5-7		6-7	
Control	91± 3	106±	4	121±	5	133±	6	142±	7	148±	8	155±	8
25ppm	91± 3	107土	4	121±	4	132±	6	143±	6	150±	6	157±	8
100ppm	91± 3	107±	4		5	133±	7	145±	7	153±	7 * *	159±	8*
400ppm	91± 3	103±	4**	115±	4* *	124±	5**	133±	5 * *	140±	5**	146±	6**

(HAN260)

ANIMAL : RAT F344/DuCrj

UNIT : g

REPORT TYPE : A1 104

SEX : FEMALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

PAGE: 8 Group Name Administration week-day_ 7-7 8-7 9-7 10-7 11-7 12-7 13-7 Control 160± 164± 10 169± 10 173± 10 176± 11 178± 11 181± 11 25ppm 162± 9 166± 9 170± 10 175± 10 179± 11 180± 11 183± 11 $100 \mathrm{ppm}$ 165± 9* $169 \pm$ 173± 10 177± 10 182± 11* 185生 11** 187土 11* 400ppm 151± 6** $155\pm$ $158 \pm$ 7** 163± 7** 166± 7** $168 \pm$ 7** 171± 7**

Significant difference; $*: P \leq 0.05$

**: $P \leq 0.01$

Test of Dunnett

(HAN260)

ANIMAL : RAT F344/DuCrj

UNIT : g REPORT TYPE : A1 104

SEX : FEMALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

Group Name Administration week-day_ 14-7 18-7 22-7 26-7 30-7 34-7 38-7

Control 189 ± 12 183± 11 197± 13 203± 14 206± 13 212± 14 217± 16 25ppm 191± 12 185± 11 199± 13 205 ± 13 209± 14 215± 15 218± 15 100ppm 190± 12* 196± 12* 208± 15 204± 13* 214± 15* 221± 15* 225± 16* 400ppm $173 \pm$ 8** 180± 8** $187 \pm$ 9** 194土 9** 199± 10* 206± 10 213± 10

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

(HAN260)

BAIS 4

ANIMAL : RAT F344/DuCrj

UNIT : g
REPORT TYPE : A1 104

SEX : FEMALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

PAGE: 10

ıp Name	Administration	week-day					
	42-7	46-7	50-7	54-7	58-7	62-7	66-7
Control	220± 17	227± 18	227± 18	230± 20	234± 20	236± 22	242± 24
25ppm	222± 17	228± 18	231± 20	236± 21	243± 22	244± 23	250± 25
100ppm	231± 16**	238± 18*	239± 18*	245± 20**	251± 22**	253± 24**	261± 24**
400ppm	213± 11*	209± 12**	210± 11**	215± 12 * *	220± 12**	220± 1 4**	225± 15**
Significant differen	nce; *: P ≦ 0.05 *	*: P ≤ 0.01		Test of Dunnett			

(HAN260)

ANIMAL : RAT F344/DuCrj

UNIT : g
REPORT TYPE : A1 104

SEX : FEMALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

PAGE: 11

p Name	Administra	tion week-day					
	70-7	74-7	78-7	82–7	86-7	90-7	94-7
Control	247± 24	252± 21	255± 22	259± 21	259± 25	269± 23	269± 26
25ррт	256± 26	259± 26	266± 27	268± 28	270± 29	278± 28	283± 28*
100ppm	265± 26 * *	* 270± 26**	275± 27**	279± 29**	281± 29**	290± 28**	295± 29**
400ppm	227± 15**	* 229± 15 **	230± 15**	229± 16**	229± 16**	230± 19**	231± 20**
significant differenc	e; $*: P \le 0.05$	** : P ≤ 0.01		Test of Dunnett			

(HAN260)

ANIMAL : RAT F344/DuCrj

UNIT : g
REPORT TYPE : A1 104

SEX : FEMALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

p Name	Administration we	ek-day			
	98-7	102-7	104-7		
Control	273± 25	274± 26	272± 27		
25ррт	284± 28	282± 31	280± 30		
100ppm	293± 30**	289± 39	295± 24 * *		
400ppm	228± 22**	218± 29**	218± 28**		
Significant difference	ee; *:P≦0.05 **	: P ≤ 0.01	Test	t of Dunnett	

(HAN260)

BAIS 4

APPENDIX E 1

FOOD CONSUMPTION CHANGES: SUMMARY,

RAT: MALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

UNIT : g

REPORT TYPE : A1 104

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

Group Name	Administration	week-day(effective)				······································		
	1-7(6)	2-7 (7)	3-7(7)	4-7(7)	5-7 (7)	6-7(7)	7-7 (7)	
Control	14.5± 1.0	15.9± 1.2	17.3± 1.4	17.5± 1.2	17.5± 1.4	17.1± 1.2	17.2± 1.2	
25ppm	14.3± 0.9	16.1± 1.1	17.5± 1.1	17.6± 1.1	17.5± 1.0	17.4± 1.0	17.3± 1.1	
100ppm	14.1± 1.1	16.2± 1.3	18.1± 1.6*	18.2± 1.6*	17.9± 1.5	18.1± 1.3**	17.8± 1.4	
400ppm	12.6± 0.9**	15.0± 1.0**	16.7± 1.4	17.2± 1.5	17.3± 1.4	17.6± 1.6	17.4± 1.4	

Significant difference;	* : P ≤ 0.05	** : P ≤ 0.01	Test of Dunnett
(HAN260)			

(HAN260)

BAIS 4

ANIMAL : RAT F344/DuCrj

UNIT : g

REPORT TYPE : A1 104

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

** : P ≤ 0.01

Group Name Administration week-day(effective) 8-7(7) 9-7(7)10-7(7)11-7(7)12-7(7)13-7(7) 14-7(7) Control 16.6± 1.3 17.2± 1.4 16.9 ± 1.4 16.8± 1.2 16.9± 1.2 16.8± 1.5 16.8± 1.4 25ppm 16.8± 1.1 17.4± 1.0 17.3± 1.1 17.1± 1.1 17.0± 1.0 16.9± 1.0 16.9 ± 1.0 100ppm 17.5± 1.2** 17.7± 1.2 17.7± 1.3** 17.4± 1.3* 17.4± 1.1 17.3± 1.2 17.4± 1.2 400ppm 17.5± 1.4** 17.6± 1.2 17.4± 1.3 17.4± 1.3* 17.7± 1.4** 17.8± 1.3** 17.9± 1.3**

Test of Dunnett

(HAN260)

Significant difference; $*: P \leq 0.05$

BAIS 4

ANIMAL : RAT F344/DuCrj

UNIT : g

REPORT TYPE : A1 104

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

p Name	Administration	week-day(effective)					
	18-7 (7)	22-7 (7)	26-7 (7)	30-7(7)	34-7(7)	38-7 (7)	42-7 (7)
Control	16.4± 1.4	17.0± 1.4	16.8± 1.4	16.2± 1.3	17.1± 1.5	16.6± 1.2	16.6± 1.4
25ppm	16.6± 0.9	17.0± 1.0	16.7± 1.3	16.2± 0.9	17.5± 1.1	16.3± 1.1	16.6± 0.9
100ррш	16.9± 1.0*	17.3± 1.1	16.8± 1.2	16.7± 0.9	17.4± 1.1	16.7± 1.2	17.0± 1.0
400ppm	17.5± 1.5**	18.0± 1.5**	17.6± 1.3*	17.3± 1.5**	17.9± 1.4**	17.1± 1.0*	16.2± 1.9

(HAN260)

ANIMAL : RAT F344/DuCrj

UNIT : g

REPORT TYPE : A1 104

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

Name	Administration	week-day(effective)_					
	46-7(7)	50-7 (7)	54-7 (7)	58-7 (7)	62-7 (7)	66-7 (7)	70-7 (7)
Control	17.2± 1.4	17.1± 1.4	16.5± 1.4	17.1± 1.4	17.5± 1.5	17.4± 1.5	17.0± 1.4
25ppm	17.2± 0.9	17.2± 0.9	17.0± 0.9	16.9± 0.9	17.1± 1.1	17.4± 1.2	17.0± 1.2
100ррт	17.1± 0.8	17.2± 0.8	17.2± 0.9	17.2± 0.9	17.2± 0.9	17.4± 0.9	17.3± 0.9
400ppm	17.8± 1.9	17.7± 1.2	17.6± 1.5**	17.4± 1.4	17.0± 1.3	16.9± 1.7	17.2± 1.5

(HAN260)

ANIMAL : RAT F344/DuCrj

UNIT : g

REPORT TYPE : A1 104

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

Group Name	Administration 74-7(7)	week-day(effective) 78-7(7)	82-7(7)	86-7(7)	90-7(7)	94-7 (7)	98-7(7)
Control	17.2± 1.3	17.6± 1.5	16.8± 2.7	17.2± 1.3	17.5± 1.5	16.8± 1.4	17.2± 1.4
25ppm	17.0± 1.6	17.4± 1.1	17.3± 1.4	16.9± 1.8	17.1± 1.1	16.7± 1.0	16.8± 1.4
100ppm	17.2± 1.0	17.5± 1.1	17.5± 1.5	17.1± 1.2	17.4± 1.7	17.0± 1.8	16.1± 4.1
400ppm	17.0± 1.4	17.2± 1.7	16.9± 2.0	16.6± 1.5	16.7± 1.6	16.5± 1.7	17.2± 2.0

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

(HAN260)

BAIS 4

ANIMAL : RAT F344/DuCrj UNIT : g

REPORT TYPE : A1 104

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

up Name	Administration 102-7(7)	week-day(effective) 104-7(7)		PAGE: 6
Control	17.6± 1.5	17.2± 1.9		
25ppm	16.8± 1.1	16.3± 1.2**		
100ppm	17.3± 2.4	17.0± 2.2		
400ppm	16.8± 2.0	16.7± 3.8		
Significant differen N260)	ce; *: P ≤ 0.05	**: P ≦ 0.01	Test of Dunnett	

(HAN260)

APPENDIX E 2

FOOD CONSUMPTION CHANGES: SUMMARY,

RAT: FEMALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

UNIT : g
REPORT TYPE : A1 104

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

Name	Administration	week-day(effective)_					
	1-7 (6)	2-7(7)	3-7 (7)	4-7 (7)	5-7 (7)	6-7(7)	7-7 (7)
Control	10.8± 0.6	11.0± 0.8	11.4± 0.9	11.5± 0.8	11.3± 0.9	11.2± 0.9	11.1± 1.0
25ppm	10.7± 0.6	11.4± 0.6*	11.6± 0.8	11.7± 0.8	11.6± 0.8	11.5± 0.9	11.4± 0.9
100ppm	10.9± 0.8	11.9± 1.0**	12.3± 1.2**	12.4± 1.1**	12.7± 1.0**	12.1± 0.9**	11.9± 1.1**
400ppm	9.8± 0.6**	11.2± 0.8	11.5± 0.7	11.9± 0.9	12.2± 0.8**	12.1± 0.8**	12.2± 0.9**
							_
Significant differen	ce; *:P≦0.05	** : P ≤ 0.01		Test of Dunnett			

(HAN260)

ANIMAL : RAT F344/DuCrj

UNIT : g
REPORT TYPE : A1 104
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

Name	Administration	week-day(effective)_					
	8-7 (7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	14-7(7)
Control	10.8± 0.8	11.2± 1.0	11.0± 1.0	11.0± 0.9	11.3± 0.9	11.1± 0.8	11.3± 0.9
25ppm	10.8± 0.9	11.2± 0.9	11.0± 0.9	11.5± 1.0*	11.3± 1.0	11.3生 0.7	11.5± 1.0
100ppm	11.4± 1.0**	11.4± 1.0	11.4± 0.8*	12.0± 1.2**	12.1± 1.2**	11.9± 1.1**	12.2± 1.3**
400ppm	12.2± 0.9 * *	12.0± 0.8**	12.0± 0.8**	12.4± 0.9**	12.6± 0.9**	12.7± 0.9**	12.8± 1.0**

(HAN260)

ANIMAL : RAT F344/DuCrj

UNIT : g REPORT TYPE : A1 104

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE: 9

Name	Administration	week-day(effective)_					
	18-7 (7)	22-7(7)	26-7 (7)	30-7(7)	34-7(7)	38-7 (7)	42-7(7)
Control	10.8± 0.9	11.3± 1.1	11.0± 1.0	10.9± 0.9	10.9± 1.0	11.3± 1.0	11.2± 1.0
25ppm	11.2± 0.9	11.6± 1.1	11.0± 0.9	10.9± 1.1	11.5± 0.9**	11.3± 1.0	11.2± 1.0
100ppm	11.4士 1.0**	11.7± 1.0	11.1± 1.3	11.4± 0.8	12.0± 1.1**	11.8± 1.1*	12.2± 1.0**
400ppm	12.6± 1.0**	12.6生 1.0**	12.3± 0.8**	12.4± 1.0 **	12.6± 0.9**	12.3± 0.8**	11.7± 0.9*

(HAN260)

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

Test of Dunnett

ANIMAL : RAT F344/DuCrj

UNIT : g
REPORT TYPE : A1 104

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

ıp Name	Administration	week-day(effective)					
	46-7 (7)	50-7(7)	54-7(7)	58-7 (7)	62-7 (7)	66-7 (7)	70-7(7)
Control	11.7± 1.1	10.9± 0.9	11.6± 1.0	11.5± 0.9	11.6± 1.1	12.0± 1.2	12.0± 1.1
25ppm	11.5± 1.0	11.4± 1.1*	11.9± 1.2	11.7± 1.1	11.5± 1.0	12.0± 1.2	12.0± 1.1
100ppm	12.0± 1.0	11.7± 0.9**	12.6± 1.1**	12.2± 1.2**	11.9± 1.1	12.7± 1.0**	12.6± 0.9**
400ppm	12.4± 1.1**	12.5± 1.1**	13.0± 1.1**	12.7± 0.9**	12.1± 1.1	12.9± 1.0**	12.6± 1.0*
Significant difference	ce; *: P ≤ 0.05	** : P ≤ 0.01		Test of Dunnett			

(HAN260)

BAIS 4

ANIMAL : RAT F344/DuCrj

UNIT : g
REPORT TYPE : A1 104

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

oup Name	Administration	week-day(effective)_					
	74-7(7)	78-7 (7)	82-7 (7)	86-7(7)	90-7(7)	94-7(7)	98-7 (7)
Control	12.1± 1.0	12.3± 1.1	12.2± 0.9	12.0± 1.4	12.8± 1.4	12.1± 1.9	12.6± 1.3
25ppm	12.0± 0.9	12.6± 1.2	12.2± 1.1	12.4± 1.4	12.5± 2.1	12.7± 1.0	13.0± 1.3
100ppm	12.5± 1.2	13.0± 1.1*	12.9± 1.2**	12.8± 1.1**	13.5± 1.3*	13.2± 1.3**	13.2± 1.9*
400ppm	12.4± I.1	12.7± 1.2	12.8± 1.1*	13.1± 1.9**	13.1± 1.9	12.8± 1.7	13.8± 2.0*
Significant difference	ce; *: P ≤ 0.05	** : P ≤ 0.01		Test of Dunnett			

(HAN260)

BAIS 4

ANIMAL : RAT F344/DuCrj

UNIT : g
REPORT TYPE : A1 104

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

roup Name	Administration	week-day(effective)	
	102-7 (7)	104-7(7)	
Control	12.4± 1.5	12.2± 1.9	
25ppm	12.6± 1.4	12.7± 1.3	
100ppm	12.8± 2.4	12.9± 2.0	
400ppm	13.2± 2.7	13.3± 3.4	
Significant difference	ce; *:P≦0.05	** : P ≤ 0.01	Test of Dunnett

(HAN260)

BAIS 4

APPENDIX F 1

HEMATOLOGY: SUMMARY,

RAT: MALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1 SEX : MALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY) ALL ANIMALS (105W)

PAGE: 1 Group Name NO. of RED BLOOD CELL HEMOGLOBIN HEMATOCRIT MCV MCH MCHC PLATELET 1 0°/µl Animals g/dl % f 🙎 рg g/dl $10^{3}/\mu l$ Control 40 8.44± 1.51 $13.9 \pm$ 2.6 $42.8 \pm$ 51.1± 3.8 6.7 16.5 \pm 1.2 $32.3 \pm$ 1.8 929± 241 25ppm 35 8.52± 1.50 13.8± 2.5 $42.9 \pm$ 6.4 $51.0 \pm$ 4.4 $16.3 \pm$ 1. 1 $32.0 \pm$ 1.9 1004± 326 100ppm 38 7.96± 1.59 13.1± 2.5 40.5 \pm 6.6 51.6± 4.6 16.5 \pm 0.9 $32.0 \pm$ 1.5 1117± 241** 400ppm 29 8.50 ± 1.73 13.4± 2.8 41.9± 7.4 49.9± 4.6 15.8 \pm 0.9* 31.8± 1.9 1045士 204 Significant difference; $*: P \leq 0.05$ **: P ≤ 0.01 Test of Dunnett

(HCL070)

ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1 SEX : MALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY) ALL ANIMALS (105W)

PAGE: 2 Group Name NO. of WBC Differential WBC (%) 1 0³/µl Animals N-BAND N-SEG EOSINO BASO MONO LYMPHO OTHER Control 40 6.50 ± 3.30 $1\pm$ 2 $47\pm$ 11 $2\pm$ $0\pm$ $5\pm$ 2 42± 11 $3\pm$ 12 25ppm 35 5.91± 2.10 1± 1 49士 8 $2\pm$ 0土 $5\pm$ 2 43± 9 1± 1 100ppm 38 6.79± 2.61 $1\pm$ 1 $51\pm$ 9 2± 0土 $5\pm$ 1 $41\pm$ $1\pm$ 1 400ppm 29 6.42± 1.97 1± 1 45± 8 $1\pm$ 1 0± $5\pm$ 2 46生 7 $2\pm$ 3 Significant difference; $*: P \leq 0.05$ ** : P ≤ 0.01 Test of Dunnett

(HCL070)

APPENDIX F 2

HEMATOLOGY: SUMMARY,

RAT: FEMALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1 SEX : FEMALE

HEMATOLOGY (SUMMARY) ALL ANIMALS (105W)

oup Name	NO. of Animals	RED BLOOD CELL 1 O⁵∕µl	HEMOGLOBIN g/dl	HEMATOCRIT %	MCV f l	MCH pg	MCHC g/dl	PLATELET 1 0³/µl
Control	36	7.98± 1.35	14.5± 2.4	42.6± 6.3	53.9± 3.3	18.2± 0.8	33.9± 1.9	658± 92
25ppm	45	8.11± 1.24	14.4± 2.3	42.8± 6.0	53.1± 3.0	17.8± 1.0	33.5± 2.0	716± 208
100ррш	37	8.05± 1.45	14.5± 2.2	43.1± 5.7	54.9± 8.7	18.3± 1.9	33.6± 1.7	721± 168
400ppm	26	7.89± 1.25	13.2± 1.6	40.7± 4.7	52.1± 4.2**	16.9± 1.3**	32.4± 1.1**	1041± 284**

(HCL070)

ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1 SEX : FEMALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY) ALL ANIMALS (105W)

PAGE: 4 Group Name NO. of WBC (%) Differential WBC 1 03/µl Animals N-BAND N-SEG EOSINO BASO MONO LYMPHO OTHER 12.46± 57.20 Control 36 $1\pm$ $39 \pm$ 11 $2\pm$ $0\pm$ 4± 2 $49\pm$ 13 $6\pm$ 21 25ppm 45 2.98± 1.48 1± 1 $41\pm$ 11 $2\pm$ 0± $4\pm$ 2 $50\pm$ 12 $2\pm$ 10 100ppm 37 3.21± 3.38 $1\pm$ $39 \pm$ 12 $2\pm$ 0± 4± 2 $52 \pm$ $2\pm$ 12 14 400ppm 26 11.62± 20.13** $1\pm$ 1 $39 \pm$ 14 $1\pm$ 1 0生 0 5± 2 $43 \pm$ 17 28 11士 Significant difference; $*: P \leq 0.05$ **: $P \leq 0.01$ Test of Dunnett

(HCL070)

APPENDIX G 1

BIOCHEMISTRY: SUMMARY,

RAT: MALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1

SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

p Name	NO. of Animals	TOTAL 1 g/dl	PROTEIN	ALBUMIN g∕dl		A/G RAT	10	T-BILI mg/dl		GLUCOSE mg/dl		T-CHOLES mg/dl	STEROL	TRIGLYC mg/dl	CERIDE
Control	40	6.5±	0.6	2.9±	0.4	0.8±	0. 1	0.17±	0.08	166士	29	200±	78	144±	150
25ppm	35	6.6±	0.3	2.9±	0.2	0.8±	0. 1	0.14±	0. 02	173±	17	189 <u>.</u> ±	61	108±	62
100ppm	38	6.6±	0.3	2.8±	0.2	0.7±	0.1**	0.15±	0.03	170±	27	241±	65*	190土	132*
400ppm	29	6.5±	0.4	2.7±	0.2**	0.7≛	0.1*	0.19±	0.13	164±	14	249±	56 **	205±	130≉

PAGE: 1

(HCL074) BAIS 4

ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1 SEX: MALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

oup Name	NO. of Animals	PHOSPHO mg/dl		GOT I U/	2	GPT I U / £		LDH I U/	٤	ALP IU/£		G-GTP IU/l		CPK IU/L	!
Control	40	284±	108	89±	69	39±	15	189±	53	214±	93	6±	4	109±	86
25ppm	35	271±	73	71±	22	35±	10	170±	38	194±	43	5±	3	92±	11
100ррш	38	333±	81**	73±	37	34±	20∗	177±	61	176±	82**	7±	4	93±	18
400ppm	29	352±	66**	121±	139	58±	54	198±	144	175±	66**	11±	8*	99±	55**

(HCL074)

ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1 SEX : MALE

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

roup Name	NO. of Animals	UREA NITROGEN mg/dl	CREATININE mg/dl	SODIUM m Eq / L	POTASSIUM m Eq / l	CHLORIDE m Eq / l	CALCIUM mg/dl	INORGANIC PHOSPHORU mg/dl
Control	. 40	24. 2± 12. 8	0.6± 0.2	142± 2	3.8± 0.4	106± 2	10.4± 0.5	4.3± 0.8
25ppm	35	21.0± 4.4	0.6± 0.1	142± 1	3.5± 0.3*	106± 1	10.4± 0.4	4.2± 0.5
100ppm	38	26.8± 12.2*	0.7± 0.3	142± 2	3.6± 0.3	107± 2	10.8± 0.7**	4.8± 1.4
400ppm	29	38.8± 70.5**	0.7± 0.7	142± 4	3.8± 0.7	111± 4**	10.7± 0.8	5.1± 2.7

(HCL074)

APPENDIX G 2

BIOCHEMISTRY: SUMMARY,

RAT: FEMALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1 SEX : FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

PAGE: 4 Group Name NO. of TOTAL PROTEIN ALBUMIN A/G RATIO T-BILIRUBIN GLUCOSE T-CHOLESTEROL TRIGLYCERIDE g/dl Animals g/đl mg/dl mg/dl mg/dl mg/dl Control 37 6.8± 0.5 3.6± 0.3 1.1± 0.1 0.14± 0.07 155士 15 124± 25 $53\pm$ 56 25ppm 45 7.0 ± 0.5 $3.6 \pm$ 0.2 1.1± 0.1 0.14生 0.04 $159\pm$ 18 $162 \pm$ 67** 114± 146** 100ppm 38 $7.0 \pm$ 0.4 $3.5 \pm$ 0.3 $1.0\pm$ 0.1* 0.23± 0.60 $163 \pm$ 20 187± 55** $118\pm$ 104** 400ppm 26 6.8± 0.8 $3.1\pm$ 0.4** 0.9± 0.1** 0.20± 0.07** 136± 22** $288 \pm$ 85** $159 \pm$ 107** Significant difference; $*: P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(HCL074)

ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1 SEX: FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

roup Name	NO. of Animals	PHOSPHO mg/dl	DLIPID	GOT I U/	<u>e</u>	GPT I U/	e	LDH I U/	£	ALP IU/J	7	G-GTP IU/s	2	CPK IU/	e
Control	37	227±	46	186±	194	75±	38	361±	667	144土	61	2±	1	125±	182
25ppm	45	287生	110**	138±	68	67±	35	243±	104	116±	53**	2±	1	92±	30
100ppm	38	321±	86**	143±	191	63±	35	236±	110	109±	64**	2±	2	91±	23
400ppm	26	437±	116**	1015±	1144**	421±	622**	618±	759**	384±	284**	26±	27**	145±	168

(HCL074)

BAIS 4

ANIMAL : RAT F344/DuCrj

MEASURE. TIME : 1 SEX : FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (105W)

roup Name	NO. of Animals	UREA NI mg/dl	TROGEN	CREATIN mg/dl	IINE	SODIUM m Eq / L		POTASSI mEq/		CHLORIDE m Eq / £		CALCIUM mg/dl	1	INORGAN mg/dl	IIC PHOSPHORUS
Control	37	20.0±	13. 7	0.5±	0.0	141±	1	3.4±	0.4	104±	2	10.3±	0.4	4.1±	0.9
25ppm	45	18.1±	2. 6	0.5±	0.1	141±	2	3.3±	0.4	104±	3	10.4±	0.3	4.0±	0.6
100ppm	38	17.7±	2.8	0.5±	0. 1	141±	1	3.3±	0.4	106±	2	10.5±	0.4	3.8±	0.8
400ppm	26	22.2±	5. 2**	0.4±	0.1**	141±	2	3.4±	0.6	109±	5**	10.6±	0.5**	4.3±	0.9

(HCL074) BAIS 4

APPENDIX H 1

URINALYSIS: SUMMARY,

RAT: MALE

URINALYSIS

ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1

SEX : MALE

REPORT TYPE : A1

PAGE: 1

up Name	NO. of	pH_								Prote	in			Gluco	se				Ket	one be	odv			Bi	irub	in .	
	Animals	5. 0	6.0	6.5	7.0	7.5	8.0	8. 5	CHI	- ±	+	2+ 3+ 4+	CHI	<u>- ±</u>	+	2+ 3	3+ 4+	CHI		± +	-	+ 4+	CHI			3+	CHI
Control	40	0	0	4	7	17	12	0		0 0	0	0 12 28		40 (0	0	0 0		39	1 0	0	0 0		40	0	0 0	
25ppm	35	0	0	2	3	18	12	0		0 0	0	1 15 19		35 (0	0	0 0		34	1 0	0	0 0		35	0	0 0	
100ppm	38	0	0	3	5	16	14	0		0 0	0	0 4 34	*	38 (0	0	0 0		38	0 0	0	0 0		38	0	0 0	
400ppm	31	0	0	8	11	11	1	0	**	0 0	0	0 5 26		31 (0	0	0 0		29	1 1	0	0 0		31	0	0 0	

(HCL101)

URINALYSIS

ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1

	REPORT	TYPE : A1		PAGE: 2
-). of nimals	Occult blood - ± + 2+ 3+ CHI	Urobilinogen ± + 2+ 3+ 4+ CHI	
Control	40	38 0 1 0 1	40 0 0 0 0	
25ppm	35	34 0 0 0 1	35 0 0 0 0	
100ppm	38	38 0 0 0 0	38 0 0 0 0	
400ppm	31	30 0 0 0 1	31 0 0 0 0	

(HCL101)

APPENDIX H 2

URINALYSIS: SUMMARY,

RAT: FEMALE

URINALYSIS

ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1

SEX : FEMALE

REPORT TYPE : A1

PAGE: 3

ıp Name	NO. of	_Hg								Protein		Glucose	Ketone body	Bilirubin
	Animals		6.0	6.5	7. 0	7. 5	8.0	8. 5	CHI	- ± + 2+ 3+ 4+	CHI	$-\pm + 2+ 3+ 4+$ CHI	- ± + 2+ 3+ 4+ CHI	- + 2+ 3+ CHI
Control	38	0	0	2	7	8	17	4		1 2 7 13 9 6		38 0 0 0 0 0	24 14 0 0 0 0	37 0 0 1
25ppm	45	0	0	4	7	11	19	4		0 1 13 10 10 11		45 0 0 0 0 0	27 16 2 0 0 0	45 0 0 0
100ppm	41	0	2	1	5	10	19	4		0 0 1 6 18 16	**	41 0 0 0 0 0	22 17 2 0 0 0	41 0 0 0
400ppm	27	0	0	6	11	5	4	1	*	0 0 0 1 8 18	**	27 0 0 0 0 0	14 12 0 1 0 0	27 0 0 0

(HCL101)

URINALYSIS

ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1

SEX : FEMALE

SEX : FEMALE	REPORT	TYPE : A1			PAGE: 4
Group Name	NO. of Animals	Occult blood - ± + 2+ 3+ CHI	Urobilinogen ± + 2+ 3+ 4+ CHI		
Control	38	38 0 0 0 0	38 0 0 0 0		
25ppm	45	43 0 0 0 2	45 0 0 0 0		
100ppm	41	39 0 0 1 1	41 0 0 0 0		
400ppm	27	27 0 0 0 0	27 0 0 0 0		
Significant	difference	; *: P ≤ 0.05 **	: P ≤ 0.01	Test of CHI SQUARE	
(HCL101)					DATO 4

BAIS 4

(HCL101)

APPENDIX I 1

GROSS FINDINGS: SUMMARY,

RAT: MALE

ALL ANIMALS

STUDY NO. : 0417 ANIMAL : RAT F344/DuCrj

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

rgan	Findings	Group Name NO. of Animals	Control 50 (%)	25ppm 50 (%)	100ppm 50 (%)	400ppm 50 (%)
kin/app	hemorrhage		0 (0)	0 (0)	0 (0)	1 (2)
	nodule		3 (6)	5 (10)	5 (10)	5 (10)
ubcutis	jaundice		1 (2)	0 (0)	0 (0)	0 (0)
	mass		5 (10)	11 (22)	8 (16)	4 (8)
	abscess		0 (0)	1 (2)	0 (0)	0 (0)
asal cavit	red		0 (0)	0 (0)	0 (0)	1 (2)
ing	red		2 (4)	0 (0)	0 (0)	2 (4)
	white zone		1 (2)	0 (0)	0 (0)	1 (2)
	red zone		1 (2)	1 (2)	2 (4)	1 (2)
	nodule		2 (4)	3 (6)	1 (2)	7 (14)
	voluminus		0 (0)	0 (0)	1 (2)	1 (2)
mph node	enlarged		2 (4)	2 (4)	2 (4)	1 (2)
ymus	red zone		0 (0)	0 (0)	0 (0)	1 (2)
leen	enlarged		5 (10)	4 (8)	5 (10)	4 (8)
	white zone		0 (0)	1 (2)	1 (2)	0 (0)
	nodule		1 (2)	0 (0)	0 (0)	3 (6)
	deformed		0 (0)	0 (0)	1 (2)	0 (0)
art	enlarged		0 (0)	0 (0)	0 (0)	1 (2)
	white zone		2 (4)	1 (2)	0 (0)	1 (2)
	nodule		0 (0)	0 (0)	0 (0)	1 (2)
in	nodule		0 (0)	0 (0)	1 (2)	0 (0)
al cavity	nodule		0 (0)	0 (0)	0 (0)	1 (2)

STUDY NO. : 0417 ANIMAL : RAT F344/DuCrj

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

rgan	Findings	Group Name Control NO. of Animals 50 (%)	25ppm 50 (%)	100ppm 50 (%)	400ppm 50 (%)
ongue	nodule	1 (2)	0 (0)	0 (0)	0 (0)
orestomach	ulcer	0 (0)	0 (0)	3 (6)	1 (2)
	erosion	0 (0)	0 (0)	1 (2)	0 (0)
l stomach	red zone	0 (0)	0 (0)	1 (2)	0 (0)
	ulcer	0 (0)	1 (2)	0 (0)	1 (2)
	erosion	0 (0)	0 (0)	0 (0)	1 (2)
mall intes	nodule	0 (0)	0 (0)	2 (4)	0 (0)
arge intes	nodule	0 (0)	0 (0)	0 (0)	4 (8)
ver	enlarged	1 (2)	3 (6)	1 (2)	1 (2)
	pale	0 (0)	0 (0)	1 (2)	0 (0)
	white zone	0 (0)	0 (0)	1 (2)	5 (10)
	nodule	2 (4)	1 (2)	5 (10)	9 (18)
	herniation	8 (16)	6 (12)	4 (8)	3 (6)
.dney	enlarged	0 (0)	1 (2)	0 (0)	0 (0)
	white zone	0 (0)	1 (2)	0 (0)	0 (0)
	granular	8 (16)	4 (8)	14 (28)	20 (40)
in bladd	dilated	0 (0)	0 (0)	0 (0)	1 (2)
	urine:marked retention	0 (0)	0 (0)	0 (0)	5 (10)
tuitary	enlarged	5 (10)	4 (8)	5 (10)	1 (2)
	atrophic	1 (2)	0 (0)	0 (0)	0 (0)
	red zone	3 (6)	4 (8)	1 (2)	1 (2)
	brown zone	0 (0)	0 (0)	1 (2)	0 (0)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE GROSS FINDINGS (SUMMARY) ALL ANIMALS (0-105\)

rgan	Findings	Group Name Control NO. of Animals 50 (%)	25ppm 50 (%)	100ppm 50 (%)	400ppm 50 (%)
ituitary	black zone	1 (2)	2 (4)	2 (4)	1 (2)
	nodule	3 (6)	0 (0)	0 (0)	2 (4)
	cyst	0 (0)	1 (2)	1 (2)	0 (0)
yroid	enlarged	2 (4)	4 (8)	5 (10)	3 (6)
Irenal	enlarged	4 (8)	4 (8)	2 (4)	1 (2)
estis	atrophic	3 (6)	2 (4)	1 (2)	2 (4)
	nodule	43 (86)	40 (80)	37 (74)	43 (86)
ididymis	nodule	0 (0)	0 (0)	0 (0)	1 (2)
ep/cli gl	nodule	2 (4)	1 (2)	1 (2)	1 (2)
ain	red zone	0 (0)	1 (2)	2 (4)	0 (0)
	yellow zone	0 (0)	0 (0)	1 (2)	0 (0)
	nodule	0 (0)	1 (2)	0 (0)	0 (0)
	deformed	0 (0)	0 (0)	1 (2)	0 (0)
	adhesion	0 (0)	1 (2)	0 (0)	0 (0)
oinal cord	red zone	1 (2)	0 (0)	0 (0)	0 (0)
re	turbid	0 (0)	1 (2)	0 (0)	0 (0)
	white	3 (6)	3 (6)	5 (10)	1 (2)
	red	0 (0)	0 (0)	1 (2)	2 (4)
mbal gl	nodule	0 (0)	1 (2)	0 (0)	1 (2)
ne	nodule	0 (0)	0 (0)	1 (2)	0 (0)
diastinum	nodule	1 (2)	0 (0)	0 (0)	0 (0)
ritoneum	nodule	0 (0)	1 (2)	6 (12)	2 (4)

ANIMAL : RAT F344/DuCrj

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

PAGE: 4

rgan	Findings	Group Name Control NO. of Animals 50 (%)	25ppm 50 (%)	100ppm 50 (%)	400ppm 50 (%)
eritoneum	mass	0 (0)	0 (0)	1 (2)	0 (0)
etroperit	mass	0 (0)	0 (0)	0 (0)	1 (2)
odominal c	hemorrhage	0 (0)	1 (2)	1 (2)	0 (0)
	ascites	1 (2)	2 (4)	2 (4)	1 (2)
oracic ca	hemorrhage	1 (2)	0 (0)	1 (2)	0 (0)
	mass	0 (0)	0 (0)	1 (2)	0 (0)
	pleural fluid	1 (2)	0 (0)	2 (4)	2 (4)
her	eye lid:nodule	0 (0)	0 (0)	1 (2)	0 (0)
	ear:nodule	0 (0)	1 (2)	0 (0)	0 (0)
	upper jaw:nodule	0 (0)	0 (0)	1 (2)	1 (2)
	nose:nodule	2 (4)	0 (0)	0 (0)	0 (0)
ole body	anemic	0 (0)	0 (0)	0 (0)	1 (2)

(HPT080)

APPENDIX I 2

GROSS FINDINGS: SUMMARY,

RAT: MALE

DEAD AND MORIBUND ANIMALS

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : MALE

		Chaus No		0 - +- 1		0.5		100		
Organ	Findings	Group Name NO. of Animals	10	Control (%)	15	25ppm (%)	12	100ppm (%)	20	400ppm (%)
skin/app	hemorrhage		0	(0)	0	(0)	0	(0)	1	(5)
	nodule		0	(0)	0	(0)	0	(0)	2	(10)
ubcutis	jaundice		1	(10)	0	(0)	0	(0)	0	(0)
	mass		0	(0)	6	(40)	1	(8)	1	(5)
	abscess		0	(0)	1	(7)	0	(0)	0	(0)
asal cavit	red		0	(0)	0	(0)	0	(0)	1	(5)
ung	red		2	(20)	0	(0)	0	(0)	2	(10)
	red zone		1	(10)	1	(7)	2	(17)	1	(5)
	nodule		0	(0)	1	(7)	0	(0)	3	(15)
	voluminus		0	(0)	0	(0)	1	(8)	1	(5)
ymph node	enlarged		1	(10)	2	(13)	1	(8)	1	(5)
ıymus	red zone		0	(0)	0	(0)	0	(0)	1	(5)
pleen	enlarged		2	(20)	4	(27)	4	(33)	2	(10)
	white zone		0	(0)	1	(7)	0	(0)	0	(0)
	nodule		1	(10)	0	(0)	0	(0)	1	(5)
eart	enlarged		0	(0)	0	(0)	0	(0)	1	(5)
	white zone		0	(0)	1	(7)	0	(0)		(5)
	nodule		0	(0)	0	(0)	0	(0)		(5)
al cavity	nodule		0	(0)	0	(0)		(0)		(5)
restomach	ulcer		0	(0)	0	(0)		(17)		(5)
	erosion		0	(0)		(0)		(8)		(0)
stomach	red zone			(0)		(0)		(8)		(0)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE

GROSS FINDINGS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

rgan	Findings	Group Name Control NO. of Animals 10 (%)	25ppm 15 (%)	100ppm 12 (%)	400ppn 20 (%)
stomach	ulcer	0 (0)	1 (7)	0 (0)	1 (5)
mall intes	nodule	0 (0)	0 (0)	2 (17)	0 (0)
arge intes	nodule	0 (0)	0 (0)	0 (0)	1 (5)
iver	enlarged	0 (0)	3 (20)	1 (8)	0 (0)
	pale	0 (0)	0 (0)	1 (8)	0 (0)
	white zone	0 (0)	0 (0)	1 (8)	1 (5)
	nodule	1 (10)	0 (0)	2 (17)	4 (20)
	herniation	3 (30)	2 (13)	0 (0)	3 (15)
dney	enlarged	0 (0)	1 (7)	0 (0)	0 (0)
	white zone	0 (0)	1 (7)	0 (0)	0 (0)
	granular	1 (10)	2 (13)	4 (33)	6 (30)
in bladd	dilated	0 (0)	0 (0)	0 (0)	1 (5)
	urine:marked retention	0 (0)	0 (0)	0 (0)	3 (15)
tuitary	enlarged	3 (30)	4 (27)	3 (25)	1 (5)
	red zone	1 (10)	1 (7)	0 (0)	0 (0)
	black zone	0 (0)	0 (0)	1 (8)	0 (0)
	nodule	1 (10)	0 (0)	0 (0)	2 (10)
yroid	enlarged	0 (0)	1 (7)	1 (8)	1 (5)
renal	enlarged	2 (20)	2 (13)	0 (0)	1 (5)
stis	atrophic	0 (0)	0 (0)	0 (0)	1 (5)
	nodule	4 (40)	7 (47)	5 (42)	14 (70)
ididymis	nodule	0 (0)	0 (0)	0 (0)	1 (5)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE

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

drgan	Findings	Group Name Control NO. of Animals 10 (%)	25ppm 15 (%)	100ppm 12 (%)	400ppm 20 (%)
rain	red zone	0 (0)	1 (7)	1 (8)	0 (0)
	yellow zone	0 (0)	0 (0)	1 (8)	0 (0)
	nodule	0 (0)	1 (7)	0 (0)	0 (0)
	adhesion	0 (0)	1 (7)	0 (0)	0 (0)
pinal cord	red zone	1 (10)	0 (0)	0 (0)	0 (0)
y e	turbid	0 (0)	1 (7)	0 (0)	0 (0)
	white	1 (10)	0 (0)	0 (0)	0 (0)
	red	0 (0)	0 (0)	1 (8)	1 (5)
mbal gl	nodule	0 (0)	1 (7)	0 (0)	0 (0)
diastinum	nodule	1 (10)	0 (0)	0 (0)	0 (0)
ritoneum	nodule	0 (0)	0 (0)	2 (17)	1 (5)
troperit	mass	0 (0)	0 (0)	0 (0)	1 (5)
dominal c	hemorrhage	0 (0)	1 (7)	1 (8)	0 (0)
	ascites	1 (10)	1 (7)	0 (0)	0 (0)
oracic ca	hemorrhage	1 (10)	0 (0)	1 (8)	0 (0)
	mass	0 (0)	0 (0)	1 (8)	0 (0)
	pleural fluid	0 (0)	0 (0)	2 (17)	2 (10)
her	upper jaw:nodule	0 (0)	0 (0)	0 (0)	1 (5)
ole body	anemic	0 (0)	0 (0)	0 (0)	1 (5)

APPENDIX I 3

GROSS FINDINGS: SUMMARY,

RAT: MALE

SACRIFICED ANIMALS

ANIMAL : RAT F344/DuCrj

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

)rgan	Findings	Group Name Contr NO. of Animals 40 (%)	rol 25ppm 35 (%)	100ppm 38 (%)	400ppm 30 (%)	
kin/app	nodule	3 (8)	5 (14)	5 (13)	3 (10)	
ubcutis	mass	5 (13)	5 (14)	7 (18)	3 (10)	
ung	white zone	1 (3)	0 (0)	0 (0)	1 (3)	
	пodule	2 (5)	2 (6)	1 (3)	4 (13)	
ymph node	enlarged	1 (3)	0 (0)	1 (3)	0 (0)	
pleen	enlarged	3 (8)	0 (0)	1 (3)	2 (7)	
	white zone	0 (0)	0 (0)	1 (3)	0 (0)	
	nodule	0 (0)	0 (0)	0 (0)	2 (7)	
	deformed	0 (0)	0 (0)	1 (3)	0 (0)	
eart	white zone	2 (5)	0 (0)	0 (0)	0 (0)	
ein	nodule	0 (0)	0 (0)	1 (3)	0 (0)	
ongue	nodule	1 (3)	0 (0)	0 (0)	0 (0)	
orestomach	ulcer .	0 (0)	0 (0)	1 (3)	0 (0)	
l stomach	erosion	0 (0)	0 (0)	0 (0)	1 (3)	
arge intes	nodule	0 (0)	0 (0)	0 (0)	3 (10)	
iver	enlarged	1 (3)	0 (0)	0 (0)	1 (3)	
	white zone	0 (0)	0 (0)	0 (0)	4 (13)	
	nodule	1 (3)	1 (3)	3 (8)	5 (17)	
	herniation	5 (13)	4 (11)	4 (11)	0 (0)	
dney	granular	7 (18)	2 (6)	10 (26)	14 (47)	
in bladd	urine:marked retention	0 (0)	0 (0)	0 (0)	2 (7)	
tuitary	enlarged	2 (5)	0 (0)	2 (5)	0 (0)	

ANIMAL : RAT F344/DuCrj

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

rgan	Findings	Group Name Control NO. of Animals 40 (%)	25ppm 35 (%)	100ppm 38 (%)	400ppm 30 (%)
ituitary	atrophic	1 (3)	0 (0)	0 (0)	0 (0)
	red zone	2 (5)	3 (9)	1 (3)	1 (3)
	brown zone	0 (0)	0 (0)	1 (3)	0 (0)
	black zone	1 (3)	2 (6)	1 (3)	1 (3)
	nodule	2 (5)	0 (0)	0 (0)	0 (0)
	cyst	0 (0)	1 (3)	1 (3)	0 (0)
nyroid	enlarged	2 (5)	3 (9)	4 (11)	2 (7)
Irenal	enlarged	2 (5)	2 (6)	2 (5)	0 (0)
stis	atrophic	3 (8)	2 (6)	1 (3)	1 (3)
	nodule	39 (98)	33 (94)	32 (84)	29 (97)
ep/cli gl	nodule	2 (5)	1 (3)	1 (3)	1 (3)
ain	red zone	0 (0)	0 (0)	1 (3)	0 (0)
	deformed	0 (0)	0 (0)	1 (3)	0 (0)
тө	white	2 (5)	3 (9)	5 (13)	1 (3)
	red	0 (0)	0 (0)	0 (0)	1 (3)
mbal gl	nodule	0 (0)	0 (0)	0 (0)	1 (3)
ne	nodule	0 (0)	0 (0)	1 (3)	0 (0)
ritoneum	nodule	0 (0)	1 (3)	4 (11)	1 (3)
	mass	0 (0)	0 (0)	1 (3)	0 (0)
dominal c	ascites	0 (0)	1 (3)	2 (5)	1 (3)
oracic ca	pleural fluid	1 (3)	0 (0)	0 (0)	0 (0)
ner	eye lid:nodule	0 (0)	0 (0)	1 (3)	0 (0)

ANIMAL : RAT F344/DuCrj

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

PAGE: 3

rgan	Findings	Group Name NO. of Animals	Control 40 (%)	25ppm 35 (%)	100ppm 38 (%)	400ppm 30 (%)
her	ear:nodule		0 (0)	1 (3)	0 (0)	0 (0)
	upper jaw:nodule		0 (0)	0 (0)	1 (3)	0 (0)
	nose:nodule		2 (5)	0 (0)	0 (0)	0 (0)

(HPT080)

APPENDIX I 4

GROSS FINDINGS: SUMMARY,

RAT: FEMALE

ALL ANIMALS

ANIMAL : RAT F344/DuCrj

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

rgan	Findings	Group Name NO. of Animals 50	Control (%)	25ppm 50 (%)	100ppm 50 (%)	400ppm 50 (%)
kin/app	nodule	1	1 (2)	1 (2)	2 (4)	3 (6)
	scab	1	1 (2)	0 (0)	0 (0)	0 (0)
ubcutis	jaundice	2	2 (4)	0 (0)	1 (2)	4 (8)
	mass	6	5 (12)	10 (20)	11 (22)	8 (16)
ung	red	() (0)	0 (0)	0 (0)	1 (2)
	white zone	(0 (0)	0 (0)	1 (2)	2 (4)
	red zone	1	1 (2)	0 (0)	0 (0)	2 (4)
	nodule	1	1 (2)	0 (0)	1 (2)	4 (8)
	voluminus	1	1 (2)	0 (0)	0 (0)	0 (0)
mph node	enlarged	1	1 (2)	0 (0)	1 (2)	0 (0)
pleen	enlarged	7	7 (14)	2 (4)	6 (12)	13 (26)
	white zone	C	(0)	0 (0)	1 (2)	0 (0)
	nodule	1	1 (2)	0 (0)	0 (0)	1 (2)
	adhesion	C) (0)	0 (0)	1 (2)	0 (0)
eart	white zone	C) (0)	1 (2)	2 (4)	0 (0)
	hypertrophy	1	1 (2)	0 (0)	0 (0)	0 (0)
ongue	nodule	C) (0)	0 (0)	2 (4)	4 (8)
orestomach	nodule	C) (0)	0 (0)	0 (0)	1 (2)
	ulcer	C) (0)	0 (0)	1 (2)	0 (0)
stomach	nodule	C) (0)	1 (2)	0 (0)	0 (0)
	ulcer	1	(2)	0 (0)	0 (0)	1 (2)
odenum	thick	C) (0)	0 (0)	0 (0)	1 (2)

ANIMAL : RAT F344/DuCrj

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

rgan	Findings	Group Name Control NO. of Animals 50 (%)	25ppm 50 (%)	100ppm 50 (%)	400ppm 50 (%)
arge intes	nodule	0 (0)	0 (0)	0 (0)	2 (4)
iver	enlarged	1 (2)	0 (0)	1 (2)	3 (6)
	white patch	0 (0)	0 (0)	0 (0)	1 (2)
	white zone	1 (2)	0 (0)	0 (0)	5 (10)
	nodule	1 (2)	0 (0)	2 (4)	41 (82)
	cyst	1 (2)	0 (0)	0 (0)	1 (2)
	deformed	0 (0)	0 (0)	1 (2)	0 (0)
	rough	2 (4)	0 (0)	4 (8)	5 (10)
	nodular	0 (0)	0 (0)	0 (0)	2 (4)
	herniation	9 (18)	9 (18)	8 (16)	6 (12)
dney	white zone	0 (0)	0 (0)	1 (2)	0 (0)
	granular	1 (2)	5 (10)	3 (6)	5 (10)
tuitary	enlarged	10 (20)	8 (16)	8 (16)	5 (10)
	red zone	6 (12)	9 (18)	7 (14)	4 (8)
	black zone	7 (14)	4 (8)	1 (2)	3 (6)
	nodule	2 (4)	4 (8)	3 (6)	1 (2)
yroid	enlarged	2 (4)	1 (2)	2 (4)	4 (8)
	nodule	0 (0)	0 (0)	0 (0)	1 (2)
renal	enlarged	0 (0)	0 (0)	0 (0)	1 (2)
ary	enlarged	0 (0)	1 (2)	0 (0)	1 (2)
	cyst	0 (0)	0 (0)	1 (2)	1 (2)
rus	enlarged	1 (2)	0 (0)	0 (0)	0 (0)

ANIMAL : RAT F344/DuCrj

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

rgan	Findings	Group Name NO. of Animals 50 (Control 25ppm %) 50 (%)	100ppm 50 (%)	400ppm 50 (%)
terus	nodule	6 (12) 5 (10)	5 (10)	3 (6)
	cyst	0 (0) 0 (0)	0 (0)	1 (2)
	invagination	1 (2) 0 (0)	0 (0)	0 (0)
	fluid:red	1 (2) 0 (0)	0 (0)	0 (0)
agina	fluid:red	1 (2) 0 (0)	0 (0)	0 (0)
rep/cli gl	nodule	2 (4) 3 (6)	5 (10)	4 (8)
rain	red zone	1 (2) 0 (0)	0 (0)	0 (0)
	nodule	0 (0) 0 (0)	0 (0)	1 (2)
inal cord	brown zone	0 (0) 0 (0)	1 (2)	0 (0)
'e	turbid	1 (2) 0 (0)	1 (2)	1 (2)
	white	2 (4) 5 (10)	2 (4)	1 (2)
ritoneum	white zone	1 (2) 0 (0)	0 (0)	0 (0)
odominal c	hemorrhage	0 (0) 0 (0)	0 (0)	7 (14)
	nodule	1 (2) 0 (0)	0 (0)	0 (0)
	ascites	1 (2) 0 (0)	0 (0)	2 (4)
oracic ca	hemorrhage	0 (0) 0 (0)	0 (0)	1 (2)
	pleural fluid	1 (2) 1 (2)	0 (0)	1 (2)
her	lower jaw:nodule	0 (0) . 0 (0)	0 (0)	1 (2)
	nose:nodule	1 (2) 0 (0)	0 (0)	0 (0)
ole body	anemic	2 (4) 0 (0)	0 (0)	2 (4)

APPENDIX I 5

GROSS FINDINGS: SUMMARY,

RAT: FEMALE

DEAD AND MORIBUND ANIMALS

STUDY NO. : 0417 ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE GROSS FINDINGS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

gan	Findings	Group Name Control NO. of Animals 12 (%)	25ppm 5 (%)	100ppm 11 (%)	400ppm 24 (%)
in/app	nodule	0 (0)	0 (0)	1 (9)	1 (4)
bcutis	jaundice	1 (8)	0 (0)	1 (9)	4 (17)
	mass	1 (8)	0 (0)	3 (27)	4 (17)
ng	red	0 (0)	0 (0)	0 (0)	1 (4)
	red zone	1 (8)	0 (0)	0 (0)	2 (8)
	nodule	0 (0)	0 (0)	0 (0)	3 (13)
	voluminus	1 (8)	0 (0)	0 (0)	0 (0)
mph node	enlarged	1 (8)	0 (0)	1 (9)	0 (0)
leen	enlarged	3 (25)	1 (20)	4 (36)	10 (42)
	nodule	1 (8)	0 (0)	0 (0)	1 (4)
art	white zone	0 (0)	0 (0)	1 (9)	0 (0)
	hypertrophy	1 (8).	0 (0)	0 (0)	0 (0)
restomach	nodule	0 (0)	0 (0)	0 (0)	1 (4)
	ulcer	0 (0)	0 (0)	1 (9)	0 (0)
stomach	ulcer	1 (8)	0 (0)	0 (0)	0 (0)
odenum	thick	0 (0)	0 (0)	0 (0)	1 (4)
rge intes	nodule	0 (0)	0 (0)	0 (0)	2 (8)
/er	enlarged	1 (8)	0 (0)	1 (9)	1 (4)
	white patch	0 (0)	0 (0)	0 (0)	1 (4)
	white zone	1 (8)	0 (0)	0 (0)	3 (13)
	nodule	0 (0)	0 (0)	0 (0)	17 (71)
	cyst	0 (0)	0 (0)	0 (0)	1 (4)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE

GROSS FINDINGS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

Group Name Control 25ppm 100ppm 400ppm Findings_ Organ___ NO. of Animals 12 (%) 5 (%) 11 (%) 24 (%) liver deformed 0 (0) 0 (0) 1 (9) 0 (0) rough 1 (8) 0 (0) 3 (27) 5 (21) nodular 0 (0) 0 (0) 0 (0) 2 (8) herniation 2 (17) 1 (20) 1 (9) 3 (13) kidney white zone 0 (0) 0 (0) 1 (9) 0 (0) granular 1 (8) 0 (0) 2 (18) 1 (4) pituitary enlarged 5 (42) 0 (0) 5 (45) 2 (8) red zone 0 (0) 0 (0) 2 (18) 1 (4) black zone 1 (8) 0 (0) 0 (0) 2 (8) nodule 0 (0) 1 (20) 0 (0) 0 (0) thyroid enlarged 0 (0) 0 (0) 1 (9) 2 (8) nodule 0 (0) 0 (0) 0 (0) 1 (4) ovary enlarged 0 (0) 0 (0) 0 (0) 1 (4) uterus nodule 1 (8) 1 (20) 0 (0) 2 (8) cyst 0 (0) 0 (0) 0 (0) 1 (4) fluid:red 1 (8) 0 (0) 0 (0) 0 (0) fluid:red vagina 1 (8) 0 (0) 0 (0) 0 (0) prep/cli gl nodule 0 (0) 0 (0) 0 (0) 1 (4) brain red zone 1 (8) 0 (0) 0 (0) 0 (0) nodule 0 (0) 0 (0) 0 (0) 1 (4) spinal cord brown zone 0 (0) 0 (0) 1 (9) 0 (0) turbid eye 1 (8) 0 (0) 1 (9) 1 (4)

STUDY NO. : 0417 ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE GROSS FINDINGS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

PAGE: 6

Organ	Findings	Group Name Control NO. of Animals 12 (%)	25ppm 5 (%)	100ppm 11 (%)	400ppm 24 (%)
eye	white	0 (0)	0 (0)	0 (0)	1 (4)
peritoneum	white zone	1 (8)	0 (0)	0 (0)	0 (0)
abdominal c	hemorrhage	0 (0)	0 (0)	0 (0)	5 (21)
	ascites	1 (8)	0 (0)	0 (0)	2 (8)
choracic ca	hemorrhage	0 (0)	0 (0)	0 (0)	1 (4)
	pleural fluid	1 (8)	1 (20)	0 (0)	1 (4)
hole body	anemic	2 (17)	0 (0)	0 (0)	2 (8)

(HPT080)

APPENDIX I 6

GROSS FINDINGS: SUMMARY,

RAT: FEMALE

SACRIFICED ANIMALS

ANIMAL : RAT F344/DuCrj

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

rgan	Findings	Group Name NO. of Animals	Control 38 (%)	25ppm 45 (%)	100ppm 39 (%)	400ppm 26 (%)
kin/app	nodule		1 (3)	1 (2)	1 (3)	2 (8)
	scab		1 (3)	0 (0)	0 (0)	0 (0)
ubcutis	jaundice		1 (3)	0 (0)	0 (0)	0 (0)
	mass		5 (13)	10 (22)	8 (21)	4 (15)
ung	white zone		0 (0)	0 (0)	1 (3)	2 (8)
	nodule		1 (3)	0 (0)	1 (3)	1 (4)
pleen	enlarged		4 (11)	1 (2)	2 (5)	3 (12)
	white zone		0 (0)	0 (0)	1 (3)	0 (0)
	adhesion		0 (0)	0 (0)	1 (3)	0 (0)
eart	white zone	·	0 (0)	1 (2)	1 (3)	0 (0)
ongue	nodule		0 (0)	0 (0)	2 (5)	4 (15)
stomach	nodule		0 (0)	1 (2)	0 (0)	0 (0)
	ulcer	•	0 (0)	0 (0)	0 (0)	1 (4)
iver	enlarged		0 (0)	0 (0)	0 (0)	2 (8)
	white zone		0 (0)	0 (0)	0 (0)	2 (8)
	nodule		1 (3)	0 (0)	2 (5)	24 (92)
	cyst		1 (3)	0 (0)	0 (0)	0 (0)
	rough		1 (3)	0 (0)	1 (3)	0 (0)
	herniation		7 (18)	8 (18)	7 (18)	3 (12)
dney	granular		0 (0)	5 (11)	1 (3)	4 (15)
tuitary	enlarged		5 (13)	8 (18)	3 (8)	3 (12)
	red zone		6 (16)	9 (20)	5 (13)	3 (12)

ANIMAL : RAT F344/DuCrj

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

)rgan	Findings	Group Name NO. of Animals	38	Control (%)	45	25ppm (%)	39	100ppm (%)	26	400ppn (%)
oituitary	black zone		6	(16)	4	(9)	1	(3)	1	(4)
	nodule		2	(5)	3	(7)	3	(8)	1	(4)
thyroid	enlarged		2	(5)	1	(2)	1	(3)	2	(8)
ndrenal	enlarged		0	(0)	0	(0)	0	(0)	1	(4)
vary	enlarged		0	(0)	1	(2)	0	(0)	0	(0)
	cyst		0	(0)	0	(0)	1	(3)	1	(4)
terus	enlarged		1	(3)	. 0	(0)	0	(0)	0	(0)
	nodule		5	(13)	4	(9)	5	(13)	1	(4)
	invagination		1	(3)	0	(0)	0	(0)	0	(0)
rep/cli gl	nodule		2	(5)	3	(7)	5	(13)	3	(12)
ye	white		2	(5)	5	(11)	2	(5)	0	(0)
odominal c	hemorrhage		0	(0)	0	(0)	0	(0)	2	(8)
	nodule		1 ((3)	0	(0)	0	(0)	0	(0)
her	lower jaw:nodule		0	(0)	0	(0)	0	(0)	1	(4)
	nose:nodule		1 ((3)	0	(0)	0	(0)	0	(0)

APPENDIX J 1

ORGAN WEIGHT, ABSOLUTE: SUMMARY,

RAT: MALE

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE UNIT: g ORGAN WEIGHT: ABSOLUTE (SUMMARY)

SURVIVAL ANIMALS (105W)

PAGE: 1

roup Name	NO. of Animals	Body	Weight	ADRE	VALS	TEST	ES	HEAR	Т	LUNG	S	KIDN	EYS
Control	40	381±	30	0.103±	0. 154	3. 787±	1.532	1.251±	0. 114	1. 421±	0. 102	2. 772±	0. 284
25ppm	35	378±	31	0.106±	0. 188	3.685±	1. 441	1.227±	0.099	1.405±	0. 128	2.732±	0. 235
100ppm	38	384±	45	0.163±	0.528	3.437±	1. 460	1. 282±	0. 103	1.462±	0. 272	2.991±	0.321**
400ppm	30	279±	32**	0.065±	0.010**	4. 229±	1. 223	1.148±	0.100**	1.375±	0.146*	2.834±	0. 261

(HCL040)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE UNIT: g

ORGAN WEIGHT: ABSOLUTE (SUMMARY)

SURVIVAL ANIMALS (105W)

Control	NO. of Animals	SPLEEN		LIYER		BRA	IN .	
	40	1. 271± 2	2, 224	11. 401±	2. 455	2.056±	0. 058	
25ppm	35	0.930±	0. 230	11.149±	1.059	2.060±	0. 045	
100ppm	38	0.989± 0	0. 250	13.099±	1. 687**	2.050±	0. 052	
400ppm	30	0.968±	0.625	13.581±	2. 917**	1.958±	0. 05 4**	

(HCL040)

APPENDIX J 2

ORGAN WEIGHT, ABSOLUTE: SUMMARY,

RAT: FEMALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE UNIT: g ORGAN WEIGHT: ABSOLUTE (SUMMARY)

SURVIVAL ANIMALS (105W)

p Name	NO. of Animals	Body	Weight	ADRE	NALS	OVAR:	IES	HEAR	T	LUNG	5	KIDN	EYS
Control	38	253±	26	0.076±	0.015	0.131±	0. 027	0.890±	0.084	1.034±	0. 205	1.738±	0. 174
25ppm	45	260±	29	0.076±	0.021	0.199±	0. 494	0.888±	0. 099	0.991±	0.072	1.776±	0. 229
100ppm	39	275±	24**	0.073±	0.008	0.131±	0.026	0.936±	0. 119	1.059±	0. 326	1.862±	0.204*
400ppm	26	199±	28**	0.094±	0.090	0.104±	0. 035**	0.880±	0.081	1.156±	0.387*	2.071±	0. 167**

PAGE: 3

(HCL040) BAIS 4

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE UNIT: g ORGAN WEIGHT: ABSOLUTE (SUMMARY)

SURVIVAL ANIMALS (105W)

oup Name	NO. of Animals	SPLEEN	LIVER	BRA	N	
Control	38	0.798± 1.043	6.543± 1.056	1.866±	0.053	
25ppm	45	0.646± 0.608	7.019± 0.902	1.855±	0.054	
100ppm	39	0.869± 1.957	7.937± 1.032	** 1.848±	0.048	
400ppm	26	0.943± 1.020	15.357± 4.930)** 1.798±	0.049**	

APPENDIX K 1

ORGAN WEIGHT, RELATIVE: SUMMARY,

RAT: MALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE UNIT: %

ORGAN WEIGHT: RELATIVE (SUMMARY)

SURVIVAL ANIMALS (105W)

Group Name Body Weight ADRENALS TESTES HEART LUNGS KTDNEYS

roup Manie	Animals	Dody	(g)	CJANGNUA	Calcai	пеакт	raile2	KINNRAP
Control	40	381±	30	0.030± 0.056	0.992± 0.395	0.331± 0.040	0.375± 0.037	0.731± 0.086
25ppm	35	378±	31	0.029± 0.051	0.979± 0.401	0.327± 0.049	0.373± 0.035	0.729± 0.107
100ppm	38	384生	45	0.041± 0.129	0.895± 0.367	0.337± 0.033	0.387± 0.101	0.789± 0.130*
400ppm	30	279±	32**	0.024± 0.006**	1.527± 0.416**	0.416± 0.050**	0.498± 0.069**	1.023± 0.100**

(HCL042)

BAIS 4

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE UNIT: %

ORGAN WEIGHT: RELATIVE (SUMMARY)

SURVIVAL ANIMALS (105W)

	NO. of Animals	SPLEEN	LIVER	BRAIN	
Control	40	0.332± 0.575	2.993± 0.600	0.543± 0.044	
25ppm	35	0.247± 0.066	2.965± 0.361	0.549± 0.050	
100ppm	38	0.262± 0.083	3.442± 0.509**	0.540± 0.051	
400ppm	30	0.342± 0.207**	4.877± 1.039**	0.711± 0.092**	

APPENDIX K 2

ORGAN WEIGHT, RELATIVE: SUMMARY,

RAT: FEMALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

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

PAGE: 3

roup Name	NO. of Animals	Body Weight (g)	ADRENALS ~	OVARIES	HEART	LUNGS	KIDNEYS
Control	38	253± 26	0.030± 0.007	0.052± 0.011	0.355± 0.052	0.415± 0.111	0.694± 0.107
25ppm	45	260± 29	0.030± 0.014	0.077± 0.189	0.346± 0.065	0.386± 0.058	0.692± 0.149
100ppm	39	275± 24**	0.027± 0.003	0.048± 0.010	0.342± 0.040	0.390± 0.147	0.682± 0.093
400ppm	26	199± 28**	0.047± 0.040**	0.052± 0.016	0.448± 0.060**	0.601± 0.281**	1.055± 0.151**

(HCL042) BAIS 4

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE UNIT: %

ORGAN WEIGHT: RELATIVE (SUMMARY)

SURVIVAL ANIMALS (105W)

oup Name	NO. of Animals	SPLEEN	LIVER	BRAIN	
Control	38	0.336± 0.506	2.612± 0.541	0.745± 0.079	
25ppm	45	0.263± 0.304	2.714± 0.342	0.722± 0.089	
100ррш	39	0.337± 0.839	2.899± 0.378**	0.678± 0.064**	
400ppm	26	0.481± 0.522**	7.969± 3.238**	0.918± 0.127**	

(HCL042)

APPENDIX L 1

HISTOPATHOLOGICAL FINDINGS:

NON-NEOPLASTIC LESIONS : SUMMARY,

RAT: MALE:

ALL ANIMALS

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

0rgan	· · · · · · · · · · · · · · · · · · ·	p Name Control of Animals on Study 50 (%) (%) (%) (%)	25ppm 50 1 2 3 4 (%) (%) (%) (%)	100ppm 50 1 2 3 4 (%) (%) (%) (%)	400ppm 50 1 2 3 4 (%) (%) (%) (%)
Integumentar	ry system/appandage)				
kin/app	squamous cell hyperplasia	<50> 0 1 0 0 (0) (2) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
	basal cell hyperplasia	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)
	epidermal cyst	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0
ubcutis	hemorrhage	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 0 0 0 0 0 0 0	<50> 0 1 0 0 (0) (2) (0) (0)
Respiratory	system)				
asal cavit	eosinophilic change:olfactory epithelium	<50> 12 28 1 0 (24) (56) (2) (0)	<50> 7 36 4 0 (14) (72) (8) (0)	<50> 5 34 5 0 (10) (68) (10) (0)	<50> 8 35 0 0 (16) (70) (0) (0)
	eosinophilic change:respiratory epithelium	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)
rade a > b c) ignificant d	1: Slight 2: Moderate 3: Man a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤ 0.0				

: RAT F344/DuCrj

ANIMAL REPORT TYPE : A1 SEX : MALE HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

PAGE: 2

		up Name of Animals on Study	Control 50	25ppm 50	100ppm 50	400ppm 50
Organ	Findings		2 3 <u>4</u> (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)
Respiratory	system)					
asal cavit	inflammation:foreign body	4 (8)	<50> 12 0 0 (24) (0) (0)	\$50> 5 6 0 0 (10) (12) (0) (0)	<50> 5 11 2 0 (10) (22) (4) (0)	3 18 1 0 (6) (36) (2) (0)
	inflammation:respiratory epithelium	0 (0)	0 0 0 0 (0) (0)	6 2 0 0 * (12) (4) (0) (0)	5 2 0 0 * (10) (4) (0) (0)	13 13 0 0 * (26) (26) (0) (0)
	respiratory metaplasia:olfactory epitheli		2 0 0 (4) (0) (0)	4 1 0 0 (8) (2) (0) (0)	0 0 0 0 0 (0) (0)	7 9 0 0 * (14) (18) (0) (0)
	respiratory metaplasia:gland	15 (30)	15 0 0 (30) (0) (0)	14 21 0 0 (28) (42) (0) (0)	16 22 0 0 (32) (44) (0) (0)	2 37 0 0 *
	squamous cell metaplasia:respiratory epit		0 0 0 0 (0) (0)	2 0 0 0 0 (4) (0) (0) (0)	1 0 0 0 0 (2) (0) (0)	16 7 0 0 ** (32) (14) (0) (0)
	hyperplasia with atypia:transitional epit		0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	1 3 0 0 (2) (6) (0) (0)
	atrophy:olfactory epithelium	0 (0)	0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	2 0 0 0 0 (4) (0) (0) (0)	11 18 1 0 * (22) (36) (2) (0)
	necrosis:olfactory epithelium	0 (0)	0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	1 0 0 0 (2) (0) (0) (0)	5 3 0 0 * (10) (6) (0) (0)

Grade

1 : Slight 2 : Moderate 3 : Marked

4 : Severe

< a > b

a: Number of animals examined at the site

b: Number of animals with lesion

c:b/a*100 (c)

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

ANIMAL : RAT F344/DuCrj

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

PAGE: 3

		Group Name No. of Animals on Study	Co 50	ontrol	25ppm 50	100ppm 50	400ppm
Organ	Findings	Grade 1 (%)	2	3 4 (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	50 1 2 3 4 (%) (%) (%) (%)
Respiratory	system)						
nasopharynx	inflammation:foreign body	0 (0)	<50> 0 (0) (0 0	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
larynx	inflammation	0 (0)	<50> 0 (0) (0 0 0 0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)
	inflammation:foreign body	0 (0)	1 (2) (0 0 0 0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	0 1 0 0 (0) (2) (0) (0)
rachea	proliferation:histiocyte	0 (0)	<50> 1 (2) (0 0 0 0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 0 0 0 0 0 0 0
ung	congestion	1 (2)	<50> 2 (4) (0 0 0 0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)
	hemorrhage	0 (0)	0 (0) (0 0 0 0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	0 2 0 0 (0) (4) (0) (0)
	inflammation	0 (0)	0 (0) (0 0 0 0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	0 1 0 0 (0) (2) (0) (0)

Grade

1 : Slight

2 : Moderate

3 : Marked

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

b b: Number of animals with lesion (c)

c:b/a*100

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

4 : Severe

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

PAGE: 4

		Group Name No. of Animals on Study		Animals on Study 50		25ppm 50				100ppm 50				400ppm 50			n			
rgan	Findings	Grade <u>1</u> (%)	2 (%)	3 (%)	(%)	<u>1</u> (%)	2 (%)	3 (%)	<u>4</u> (%)	-	<u>1</u> (%)	2 (%)	3 (%)	(%)	·	<u>1</u> (%)	<u>2</u> (%)	3		(%)
Respiratory	system)																			
ung	inflammatory infiltration	0 (0)	<500 0 (0) (0	0 (0)	0 (0)	0	0 (0)	0 (0)	(0	<5 1 2)	0> 0 (0)	0 (0)	(0 0) ((0)	50> (0 0)
	accumulation of foamy cells	0 (0)	1 (2) (0	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	(0 0) (1 2)	0 (0)	0 (0)	(0	0	(0		0 0)
	bronchiolar-alveolar cell hyperplasia		0 (0) (0	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	. (2 4) (0 0)	0 (0)	0 (0)	(3 6) (0 (0)	((0 0)
Hematopoiet:	ic system}																			
one marrow	granulation	1 (2)	<50X 0 (0) (0	0 ()	1 (2)	0	0 (0)	0 (0)	(0	<5 0 0)	0> 0 (0)	0 (0)	(0	(0)	50> (0		0 0)
	increased hematopoiesis	2 (4)	0 (0) (0	0 0)	2 (4)	1 (2)	0 (0)	0 (0)	(3 6) (0 0)	0 (0)	0 (0)	(2 4) (0	(0		0 0)
	myelofibrosis	0 (0)	0 (0) (0	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	(0 0) (0 0)	0 (0)	0 (0)	(0 0) (0	0 (0 0)
	granulopoiesis:increased	0 (0)	0 (0) (0 (0)	0 0)	1 (2)	0 (0)	0 (0)	0 (0)	(1 2) (0	0 (0)	0 (0)	(0 0) (0 (0)	0 (0 0)

Grade 1 : Slight

2 : Moderate

3 : Marked 4 : Severe

(a) b

a: Number of animals examined at the site

b : Number of animals with lesion

(c) c:b/a * 100

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

SEX

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

: MALE

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

PAGE: 5

		Group Name No. of Animals on Study	Control 50	2 5ppm 50	100ppm	400ppm
rgan	Findings	Grade 1 (%)	2 3 4 (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	50 1 2 3 4 (%) (%) (%) (%)
(Hematopoieti	c system)					
ymph node	lymphadenitis	0 (0)	<50> 0 0 0 (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>	(50) 0 0 0 0 (0) (0) (0) (0)
spleen	congestion	0 (0)	<50> 0 0 0 (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)	<50> 0 0 0 0 0 0 0 0 0 0 0
	angiectasis	0 (0)	0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (0)
	deposit of hemosiderin	10 (20)	22 0 0 (44) (0) (0)	8 25 2 0 (16) (50) (4) (0)	5 30 0 0 (10) (60) (0) (0)	7 32 3 0 * (14) (64) (6) (0)
	fibrosis	0 (0)	1 0 0 (2) (0) (0)	0 1 0 0 (0) (2) (0) (0)	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0 (0) (0)
	extramedullary hematopoiesis	0 (0)	2 1 0 (4) (2) (0)	0 4 0 0 (0) (8) (0) (0)	0 8 0 0	0 4 2 0 (0) (8) (4) (0)
(Circulatory	system)					
neart	thrombus	0 (0)	<50> 1 0 0 (2) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)

(HPT150)

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

SEX : MALE

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

PAGE: 6

)rgan	Findings	Group Name No. of Animals on Study Grade 1 (%)		<u>4</u> (%) <u>1</u> (%)	25ppm 50 2 3 (%) (%)	<u>1</u> (%)	50 2 3 (%) (%)	9pm 4 (%)	400p 50 1 2 3 (%) (%) (%)	opm 4 (%)
(Circulatory	system}									
leart	fibrosis:focal	0 (0) (<50> 3 0 6) (0) (0 0 0	<50> 1 0 (2) (0) (0 0 0	<50> 1 1 (2) (2)	0 (0)	<50> 1 0 0 (2) (0) (0)	0 (0)
	myocardial fibrosis	22 (44) (17 0 34) (0) (0 14 0) (28)	13 0 (26) (0) (0 * 21 0) (42)	10 0 (20) (0)	0 (0)	20 12 0 (40) (24) (0)	0 (0)
Digestive sy	rstem)									
ooth	inflammation	0 (0) (<50> 1 0 2) (0) (0 0 0	<50> 1 0 2) (0) (0 0	<50> 0 0 (0) (0)	0 (0)	<50> 1 2 0 (2) (4) (0)	0 (0)
ongue	arteritis	0 (0) (<50> 2 0 4) (0) (0 1 0) (2)		0 0	<50> 0 0 (0) (0)	0 (0)	<50> 1 0 0 (2) (0) (0)	0 (0)
alivary gl	abscess	0 (0) (<50> 0 0 0) (0) (0 0 0	<50> 1 0 2) (0) (0 0 0) (0)	<50> 0 0 (0) (0)	0 (0)	<50> 0 0 0 (0) (0) (0)	0 (0)
tomach	basal cell hyperplasia	0 (0) (<50> 0 0 0) (0) (0 0 0 0) (0) (<50> 0 0 0) (0) (0 0	<50> 0 0 (0) (0)	0 (0)	(50) 1 0 0 (2) (0) (0)	0 (0)

b

b : Number of animals with lesion

(c)

c:b/a*100

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

(HPT150)

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

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

PAGE: 7

		Group Name No. of Animals on Study		50					50	Бррт			50		•				40 50	0ppm	
rgan	Findings	Grade	1 %)	2 (%)	(%)	(%)	(%)	(%)	<u>3</u> (%) (%	<u>.</u> <u>1</u>	3)	(%)	(%)	(%)		(%)	(%)	(%	5)	(%)
Digestive	system}																				
tomach	erosion:forestomach		0 0) (<50 0 0) (0	0 (0)	0 (0)	0 (0)				;) (<50 0 0)	0 (0)	0 (0)	(1 2)	0 (0)	50> 0 (0))) (0 0)
	ulcer:forestomach		0 0) (0 0) (0 0)	0 (0)	0 (0)	1 (2)	0	0 (0) (2	:) (4 8)	0 (0)	0 (0)	(1 2)	2 (4)	0)))) (0 0)
	hyperplasia:forestomach	((0 0) (1 2) (0	0 (0)	0 (0)	0 (0)	(0	0 (0		;) (0	0 (0)	0 (0)	(3 6)	0	0)))) (0 0)
	inflammation:forestomach		0 0) (0 0) (0	0 (0)	0 (0)	0 (0)	0 (0)) (0)) (1 2) (0 (0)	0 (0)	(0 0)	0 (0)	0)) (0 0)
	erosion:glandular stomach	1 (2	1 2) (1 2) (0	0 (0)	0 (0)	0 (0)	0 (0)	0 (0) (0) (0	0 (0)	0 (0)	(2 4)	0	0 (0) (0 0)
	ulcer:glandular stomach		0 0) (0 0) (0 0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0		· ·) (0	0 (0)	0 (0)	(0 0)	0	0		0 0)
iver	herniation		0 0) (1	<501 7 [4] (0	0 (0)	0 (0)	6 (12)	50> 0 (0)	0 (0			<50 4 8) () 0 (0) (0 (0)	(0	5	50> 0 (0		0 0)
	angiectasis		0 0) (0 0) (0 0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0			1 2) (0 () (0	(0 0)	0 (0)	0 (0		0 0)

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

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

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

(HPT150)

: RAT F344/DuCrj ANIMAL

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

PAGE: 8

Organ	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)		100ppm 50 1 2 3 4 (%) (%) (%) (%)	400ppm 50 1 2 3 4 (%) (%) (%) (%)
or Bait	rindings	(%) (%) (%)	(%) (%) (%) (%)	(%) (%) (%) (%)	(%) (%) (%) (%)
(Digestive	system)				
liver	necrosis:central	<50> 0 0 0 0 (0) (0) (0) (0		<50> 0 2 0 0 (0) (4) (0) (0)	<50> 0 2 0 0 (0) (4) (0) (0)
	necrosis:focal	0 0 0 0 0 (0) (0) (0		0 0 0 0 0 (0) (0)	0 2 0 0 (0) (4) (0) (0)
	spongiosis	0 0 0 0 0 (0) (0) (0	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)
	mineralization	0 2 0 0 (0) (4) (0) (0		0 1 0 0 (0) (2) (0) (0)	0 1 0 0 (0) (2) (0) (0)
	degeneration:central	0 0 0 0 0 0 0 0		0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	granulation	0 1 0 0 (0) (2) (0) (0)		0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	inflammatory cell nest	0 0 0 0 0 (0) (0) (0)		0 2 0 0 (0) (4) (0) (0)	0 1 0 0 (0) (0) (0)
	clear cell focus	7 9 0 0 (14) (18) (0) (0)	9 4 0 0 (18) (8) (0) (0)	17 12 0 0 * (34) (24) (0) (0)	0 13 27 0 *

Grade 1 : Slight

2 : Moderate

4 : Severe

< a >

a : Number of animals examined at the site

b

b: Number of animals with lesion

(c)

c:b/a * 100

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

(HPT150)

^{3 :} Marked

SEX

: RAT F344/DuCrj ANIMAL

: MALE

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

REPORT TYPE : A1

PAGE: 9

Organ	Findings	Group Name Control No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	25ppm 50 1 2 3 4 (%) (%) (%) (%)	100ppm 50 1 2 3 4 (%) (%) (%) (%)	400ppm 50 1 2 3 4 (%) (%) (%) (%)
{Digestive s	system}				
liver	acidophilic cell focus	<50> 0 1 0 0 (0) (2) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 2 1 0 0 (4) (2) (0) (0)	<50> 7 13 0 0 ** (14) (26) (0) (0)
	basophilic cell focus	2 1 0 0 (4) (2) (0) (0)	0 1 0 0 (0) (2) (0) (0)	2 5 0 0 (4) (10) (0) (0)	1 8 0 0 * (2) (16) (0) (0)
	vacuolated cell focus	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 1 0 0 (2) (2) (0) (0)
	spongiosis hepatis	0 3 0 0 (0) (6) (0) (0)	1 1 0 0 (2) (2) (0) (0)	2 3 0 0 (4) (6) (0) (0)	0 3 0 0
	bile duct hyperplasia	2 47 0 0 (4) (94) (0) (0)	0 47 0 0 (0) (94) (0) (0)	2 46 1 0 (4) (92) (2) (0)	5 41 0 0 (10) (82) (0) (0)
pancreas	atrophy	<50> 3 6 0 0 (6) (12) (0) (0)	<50> 1 13 0 0 (2) (26) (0) (0)	<50> 1 7 1 0 (2) (14) (2) (0)	<50> 3 5 0 0 (6) (10) (0) (0)
	hyperplasia	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)
	arteritis	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)	0 1 0 0 (0) (2) (0) (0)

Grade < a > 1 : Slight 2 : Moderate

3 : Marked

4 : Severe

a: Number of animals examined at the site

b: Number of animals with lesion b (c)

c:b/a*100

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

: RAT F344/DuCrj ANIMAL

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

REPORT TYPE : A1

SEX : MALE

PAGE: 10

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50 2 3 4 (%) (%) (%)	25ppm 50 1 2 3 4 (%) (%) (%) (%)	100ppm 50 1 2 3 4	400ppm 50 1 2 3 4
	Titaligo	(%)	(%) (%) (%)	(%) (%) (%) (%)	(%) (%) (%)	(%) (%) (%) (%)
{Digestive s	ystem)					
pancreas	islet cell hyperplasia	(0) (<50> 2 0 0 (4) (0) (0)	(50) 0 1 0 0 (0) (2) (0) (0)	<50> 0 2 0 0 (0) (4) (0) (0)	<50> 0 0 0 0 0 0 0 0 0 0
Urinary sys	tem)					
idney	hyperplasia:tubular epithelial cell	0 (0) (<50> 0 0 0 (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 0 1 1 0 (0) (2) (2) (0)
	infarct	0 (0) (0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0 (0) (0)
	inflammation	0 (0) (0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)
	inflammatory infiltration	0 (0) (0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	chronic nephropathy	6 (12) (28 6 2 (56) (12) (4)	5 35 3 1 (10) (70) (6) (2)	1 27 13 5 (2) (54) (26) (10)	2 28 14 2 (4) (56) (28) (4)
	pyelitis	0 (0) (0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)

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

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

(HPT150)

ANIMAL : RAT F344/DuCrj

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

]		Control 50 2 3 4	25ppm 50 <u>1 2 3 4</u>	100ppm 50 1 2 3 4	400ppm 50 <u>1 2 3 4</u>
rgan	Findings	(%)	(%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	(%) (%) (%) (%)
Urinary syste	em}					
idney	mineralization:papilla	1 (2) (<50> 0 0 0 0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
	mineralization:pelvis		1 0 0 2) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (0)
cin bladd	simple hyperplasia:transitional epithe		<50> 0 0 0 0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
Indocrine sys	stem}					
ituitary	angiectasis		<50> 0 0 0 0) (0) (0)	\(\langle 50 \rangle \) \[1 0 0 0 \\ (2) (0) (0) (0) (0) \]	(50) 0 1 0 0 (0) (2) (0) (0)	(50) 0 1 0 0 (0) (2) (0) (0)
	cyst		1 0 0 2) (0) (0)	1 2 0 0 (2) (4) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)
	deposit of hemosiderin	1 (2) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0) (0)

ANIMAL

: RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : MALE

PAGE: 12 Group Name Control 25ppm 100ppm 400ppm

Organ	Findings	No. of Animals on Study 50 Grade 1 2 3 4 (%) (%) (%) (%)	50 1 2 3 4 (%) (%) (%) (%)	50 1 2 3 4 (%) (%) (%) (%)	50 1 2 3 4 (%) (%) (%) (%)
{Endocrine sy	ystem}				
pituitary	hyperplasia	<50> 4 6 0 0 (8) (12) (0) (0)	<50> 3 4 0 0 (6) (8) (0) (0)	<50> 4 4 0 0 (8) (8) (0) (0)	<50> 2 1 0 0 (4) (2) (0) (0)
	Rathke pouch	0 0 0 0 0 (0) (0)	3 0 0 0 0 (6) (6) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
thyroid	follicular hyperplasia	<50> 0 1 0 0 (0) (2) (0) (0)	<50> 0 2 0 0 (0) (4) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 1 0 (0) (0) (2) (0)
	C-cell hyperplasia	1 4 3 0 (2) (8) (6) (0)	2 4 1 0 (4) (8) (2) (0)	8 2 0 0 * (16) (4) (0) (0)	2 3 0 0 (4) (6) (0) (0)
adrenal	angiectasis	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 0 1 0 0 (0) (2) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
	hyperplasia:cortical cell	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)
	hyperplasia:medulla	0 5 0 0 (0) (10) (0) (0)	1 1 0 0 (2) (2) (0) (0)	1 2 0 0 (2) (4) (0) (0)	2 3 0 0 (4) (6) (0) (0)

Grade

1 : Slight

2 : Moderate

3 : Marked

4 : Severe

< a >

b

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

(c)

c:b/a*100

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

(HPT150)

ANIMAL : RAT F344/DuCri

REPORT TYPE : A1

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

Group Name Control 25ppm 100ppm 400ppm No. of Animals on Study 50 50 50 Grade Organ____ Findings_ (%) (%) (%) (%) {Reproductive system} testis <50> atrophy 2 0 0 0 1 0 0 (0)(4)(0)(0) (0)(4)(0)(0) (0)(2)(0)(0) (0)(4)(0)(0) mineralization 0 0 0 0 1 0 0 0 (0)(0)(0)(0) (2)(0)(0)(0) (0)(2)(0)(0) (0)(2)(0)(0) arteritis 1 2 0 0 3 2 0 0 0 4 (2)(4)(0)(0) (6)(4)(0)(0) (0)(8)(0)(0) (0)(0)(0)(0) interstitial cell hyperplasia 5 9 2 0 0 3 4 0 0 (12) (6) (0) (0) (16) (10) (0) (0) (18) (4) (0) (0) (6)(8)(0)(0) prostate <50> <50> <50> inflammation 0 0 0 2 0 0 2 0 0 0 0 2 0 0 (0)(0)(0)(0) (0)(4)(0)(0) (0)(4)(0)(0) (0)(4)(0)(0) hyperplasia 1 2 2 0 3 4 2 0 3 2 1 0 5 6 1 0 (2) (4) (4) (0) (6)(8)(4)(0) (6)(4)(2)(0) (10) (12) (2) (0) prep/cli gl <50> duct ectasia 0 1 0 0 0 0 0 0 0 1 0 0 0 0 0 0 (0)(2)(0)(0) (0)(0)(0)(0) (0)(2)(0)(0) (0)(0)(0)(0)

Grade 1 : Slight

2 : Moderate

3 : Marked

4 : Severe

< a >

a: Number of animals examined at the site

b: Number of animals with lesion

(c) c:b/a*100

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

(HPT150)

b

BAIS4

: RAT F344/DuCrj

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

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

PAGE: 14

		Group Name No. of Animals on Study	Control 50	25ppm 50	100ppm 50	400ppm 50
rgan	Findings	Grade 1 (%)	2 3 4 (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)
Vervous sy	stem)					
rain	angiectasis	0 (0)	<50> 0 0 0 (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
	hemorrhage	0 (0)	0 0 0 0 (0) (0)	1 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	gliosis	0 (0)	0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (0)
Special se	nse organs/appendage}					
/e	cataract	3 (6)	<50> 0 0 0 (0) (0) (0)	4 0 0 0 (8) (0) (0) (0)	<50> 6 0 0 0 (12) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)
	retinal atrophy	2 (4)	0 0 0 0 (0) (0)	2 1 0 0 (4) (2) (0) (0)	0 6 0 0*	0 2 0 0 (0) (4) (0) (0)
	keratitis	0 (0)	0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)
	iritis	0 (0)	0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	2 0 0 0 0 (4) (0) (0) (0)

Grade < a > 1 : Slight

2 : Moderate

3 : Marked

4 : Severe

a : Number of animals examined at the site

b

b: Number of animals with lesion

(c)

c:b/a * 100

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

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : MALE

_		Group Name Control No. of Animals on Study 50 Grade 1 2 3 4	25ppm 50 <u>1 2 3 4</u>	100ppm 50 <u>1 2 3 4</u>	400ppm 50 _1 2 3 4
Organ	Findings	(%) (%) (%)	(%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	(%) (%) (%) (%)
{Special sens	se organs/appendage}				
еуе	squamous cell metaplasia:cornea	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)
nasolacr d	inflammation	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)	<50> 0 0 0 0 0 0 0 0 0 0 0
	squamous cell metaplasia	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)
(Musculoskele	etal system)				
muscle	hemorrhage	0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>
bone	osteosclerosis	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	\$50> 1 0 0 0 (2) (0) (0) (0)
{Body cavitie	(28				
adipose	granulation	(50) 0 1 0 0 (0) (2) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	<pre></pre>
Grade (a > b (c)	1: Slight 2: Moderate 3 a: Number of animals examined at the si b: Number of animals with lesion c: b/a * 100	: Marked 4 : Severe te			

APPENDIX L 2

HISTOPATHOLOGICAL FINDINGS:

NON-NEOPLASTIC LESIONS : SUMMARY,

RAT: MALE:

DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

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

PAGE: 1

_	No Gr	oup Name , of Animals on Study ade <u>1</u>	10 2	3	4_	_1	15 2	3	4	_1_	2	12 3	ppm 4_	_1_	2	400p 20 3	4
Organ	Findings	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Integumentar	y system/appandage)																
subcutis	hemorrhage	0 (0)	0 (0) (0	0 (0)	0 (0)	<15 0 (0) (0	0 (0)	0 (0)	0		0 (0)	0 (0)	1	20> 0 (0)	0 (0)
Respiratory	system}																
asal cavit	eosinophilic change:olfactory epithelium		<10 4 (40)	0	0 (0)	4 (27)	<15 9 (60) (0	0 (0)	2 (17)	3	12> 1 (8)	0 (0)	3 (15)	12	20> 0 (0)	0 (0)
	inflammation:foreign body	1 (10)	1 (10)	0 (0) (0 (0)	(7)	0 (0) (0 (0)	0	1 (8)	4 (33)	0 (0)	0 (0)	1 (5)	8 (40)	1 (5)	0 (0)
•	inflammation:respiratory epithelium	0 (0)	0 (0) (0 (0)	0 (0)	2 (13)	0 (0) (0 (0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	6 (30)	3 (15)	0 (0)	0 *
	respiratory metaplasia:olfactory epithel		1 (10) (0 (0)	0 (0)	2 (13)	0 (0 (0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (15)	2 (10)	0 (0)	0 (0)
	respiratory metaplasia:gland	5 (50)	1 (10) (0 (0)	0 (0)	3 (20)	6 (40) (0 (0 (0)	6 (50)	1 (8)	0 (0)	0 (0)	0 (0)	15 (75)	0 (0)	0 *
	squamous cell metaplasia:respiratory epi		0 (0) (0 (0)	0 (0)	1 (7)	0 (0)	0 (0)	0	0 (0)	0 (0)	0 (0)	0 (0)	4 (20)	4 (20)	0 (0)	0 (0)

< a >

a: Number of animals examined at the site

b b : Number of animals with lesion

(c) c:b/a*100

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

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : MALE

PAGE: 2

		Group Name No. of Animals on Stud	ly	1	Cont	rol					15	25p	pm				12	100p	pm				20	400	ppm	
rgan	Findings	Grade	(%)	(%)	(%)		<u>4</u> %)		1 (%)	(%)		3 (%)	(%)		(%)	(9	6)	3 (%)	(%)		(%)		2 %)	3 (%)	(<u>4</u> (%)
Respiratory :	system)																									
uasal cavit	hyperplasia with atypia:transitional		0	0	.0> 0 (0)		0 0)	(0 0)	0		0	0 (0)	(0		<12>))) (0	0 (0)	(1 5)		<20 0 0) (0	()	0 0)
	atrophy:olfactory epithelium	(0	0 (0)	0 (0)		0 0)	(0	0 (0)) (0	0 (0)	(1 8)	(())) (0	0 (0)	(1 5)	10) 0) (1 5)	(0)
	necrosis:olfactory epithelium	(0	0 (0)	0 (0)		0 0)	(0 0)	0 (0)) (0 0)	0 (0)	(1 8)	(())) (0	0 (0)	(1 5)	(10	2 0) (0 0)	(0 0)
asopharynx	inflammation:foreign body	(0 0) (0	.0> 0 (0)		0 0)	(0 0)	0		0	0 (0)	(1 8)	((<12>))) (0	0 (0)	(0 0)		<20 0 0) (0	(0 0)
arynx	inflammation	(0 0) (0	.0> 0 (0)		0 0)	(0 0)	0		0	0 (0)	(0 0)	(<12>))) (0	0 (0)	(1 5)	((<20 0 0) (0	(0 0)
ing	congestion	(1 10) (2	0 (0)		0 0)	(0 0)	0		0	0	(0		<12>))) (0 0)	0 (0)	(0 0)		<20: 1 5) (0	(0 0)
	hemorrhage	(0 0) (0 (0)	0 (0)		0 0)	(0 0)	0	(0 0)	0 (0)	(0	((0 0)	0 (0)	(0 0)		2 0) (0 0)	(0 0)

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

(HPT150)

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1 SEX

: MALE

PAGE: 3

		Group Name No. of Animals on Study	C 10	ontro	I		1	25 ₁	ppm			1:	100p	pm					400pp	m
gan	Findings	Grade 1 (%)	2	3 (%)	(%)	<u>1</u> (%)	2 (%)	(%)	(%)	(1 %)	2 (%)	3 (%)	(%)	-	(%)	(%)		3 (%)	(%)
despiratory	system)																			
ling	inflammation	0 (0)	<10> 0 (0) (0	0 0)	0 (0)	0	5> 0 (0)	0 (0)		0 0) (<1: 0 0)	2> 0 (0)	0 (0)	(0	1		0 0) (0
	inflammatory infiltration	0 (0)	0 (0) (0 (0 0)	0 (0)	0 (0)	0 (0)	0 (0)		0 0) (1 8)	0 (0)	0 (0)	(0 0)	0 (0)		0 0) (0 (0)
	accumulation of foamy cells	0 (0)	1 (10) (0 (0 0)	0 (0)	0 (0)	0 (0)	0 (0)		0 0) (1 8)	0 (0)	0 (0)	(0	0 (0)) (0	0 (0)
	bronchiolar—alveolar cell hyperplasia		0 (0) (0 (0 0)	0 (0)	0 (0)	0 (0)	0 (0)		0 0) (0 0)	0 (0)	0 (0)	(:	2 10)	0 (0)		0 (0)	0
lematopoieti	c system}																			
one marrow	increased hematopoiesis	0 (0)	<10> 0 (0) (0	0 0)	2 (13)	1	5> 0 (0)	0 (0)		2 7) (<1: 0 0)	(0) (0)	0 (0)	(:	2 10)	0		0 0) (0
	granulopoiesis:increased	0 (0)	0 (0) (0 0) (0 0)	(7)	0 (0)	0 (0)	0 (0)		0 0) (0 0)	0 (0)	0 (0)	(0	0 (0)		0 (0)	0 (0)
pleen	deposit of hemosiderin	1 (10)	<10> 6 (60) (0 0) (0 0)	2 (13)	<1 5 (33)	2	0 (0)		1 8) (<11 8 67)	2> 0 (0)	0 (0)	(1 5)	13		2 10) (0 (0)

(HPT150)

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : MALE

Organ	N	roup Name Control p. of Animals on Study 10 rade 1 2 3 4 (%) (%) (%) (%)	25ppm 15 1 2 3 4 (%) (%) (%) (%)	100ppm 12 12 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)
{Hematopoiet	cic system}				
spleen	extramedullary hematopoiesis	0 1 1 0 (0) (10) (10) (0)	(15) 0 4 0 0 (0) (27) (0) (0)	(12) 0 3 0 0 (0) (25) (0) (0)	<20> 0 3 2 0 0 0) (15) (10) (0)
Circulatory	system}				
eart	myocardial fibrosis	3 4 0 0 (30) (40) (0) (0)	6 4 0 0 (40) (27) (0) (0)	2 4 0 0 (17) (33) (0) (0)	<20> 8 5 0 0 (40) (25) (0) (0)
Digestive s	ystem}				
alivary gl	abscess	0 0 0 0 (0) (0) (0) (0)	0 1 0 0 (0) (7) (0) (0)	0 0 0 0 (0) (0) (0) (0)	<20> 0 0 0 0 0 0 0 0 0 0 0
tomach	basal cell hyperplasia	<10> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<15> 0 0 0 0 0 0 0 0 0 0 0	<12> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<20> 1 0 0 0 (5) (0) (0) (0)
	erosion:forestomach	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (8) (0) (0) (0)	1 0 0 0 0 (5) (0) (0)
rade a > b c) ignificant (1: Slight 2: Moderate 3: a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤ 0				

(HPT150)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1
SEX : MALE

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

PAGE : 5

0	Die 14	Group Name Control No. of Animals on Study 10 Grade 1 2 3	25ppm 15 <u>1 2 3 4</u>	100ppm 12 12 3 4 (%) (%) (%) (%)	400ppm 20 1 2 3 4 (%) (%) (%) (%)
Organ	Findings	(%) (%) (%)	(%) (%) (%) (%)	(%) (%) (%)	(%) (%) (%)
(Digestive	system)				
tomach	ulcer:forestomach	0 0 0 (0) (0) (0) ((15) 0 0 1 0 0 0) (0) (7) (0) (0)	<12> 0 4 0 0 0 0 (33) (0) (0)	<20> 0 2 0 0 0 0 (10) (0) (0)
	inflammation:forestomach	0 0 0 (0) (0) (0 0 0 0 0	0 1 0 0 (0) (8) (0) (0)	0 0 0 0 0 (0) (0)
	erosion:glandular stomach	0 1 0 (0) (10) (0) (0 0 0 0 0	0 0 0 0 0 (0) (0)	1 0 0 0 0 (5) (0) (0) (0)
	ulcer:glandular stomach	0 0 0 (0) (0) (1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	1 0 0 0 0 (8) (0) (0) (0)	0 0 0 0 0 (0) (0)
iver	herniation	<10> 0 2 0 (0) (20) (0) ((15) 0 2 0 0 0) (0) (13) (0) (0)	<12> 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<20> 0 4 0 0 (0) (20) (0) (0)
	angiectasis	0 0 0 (0) (0 0 0 0 0	0 1 0 0 (0) (8) (0) (0)	0 0 0 0 0 (0) (0)
	necrosis:central	0 0 0 (0) (0) (0 1 0 0	0 2 0 0 (0) (17) (0) (0)	0 2 0 0 (0) (10) (0) (0)
	necrosis:focal	0 0 0 (0) (0) (0 0 0 0 0	0 0 0 0 0 (0) (0) (0)	0 2 0 0 (0) (10) (0) (0)

4 : Severe

Grade 1: Slight 2: Moderate 3: Marked

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

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

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

SEX

: RAT F344/DuCrj

ANIMAL REPORT TYPE : A1

: MALE

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

PAGE: 6

		Group Name No. of Animals on Study	Control 10		25ppm 15			100ppm 12			400ppm		i					
Organ	Findings	Grade 1 (%)	(%)	(%)	(%)	<u>1</u> (%)	(%)	3	(%)	(%)	(%	3	4 (%)	<u>1</u> (%)	2 (%)			4 (%)
Digestive	system)																	
liver	spongiosis	0 (0)	0	0 (0)	0 (0)	0 (0)	0	15> 0 (0)	0 (0)	0 (0)	0		0 (0)	0 (0)				0 0)
	mineralization	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0	0 (0)	0 (0)	1 (5)	0) ())) (0 0)
	degeneration:central	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (7)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0	0 (0)	0 (0)	0 (0)	0 (0))) (0
	inflammatory cell nest	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)		0 (0)	0 (0)	0 (0))) (0
	clear cell focus	0 (0)		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	7 (35)	4) (20		0
	acidophilic cell focus	0 (0)		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (10)	4 (20)			0 0)
	basophilic cell focus	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (15)	0	i) (0
	spongiosis hepatis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)	: i) (0

Grade 1 : Slight < a >

2 : Moderate

3 : Marked

4 : Severe

b

a : Number of animals examined at the site

b : Number of animals with lesion

(c) c:b/a * 100

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

ANIMAL : RAT F344/DuCrj

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

PAGE: 7

Organ	Group No. of Grade Findings	Animals on Study 10 1 2 3 4 (%) (%) (%) (%)	25ppm 15 1 2 3 4 (%) (%) (%) (%)	100ppm 12 1 2 3 4 (%) (%) (%) (%)	400ppm 20 1 2 3 4 (%) (%) (%) (%)
<u></u>				(III) (III) (III)	(4) (4) (4)
Digestive	system)				
iver	bile duct hyperplasia	2 7 0 0 (20) (70) (0) (0)	<15> 0 12 0 0 (0) (80) (0) (0)	2 8 1 0 (17) (67) (8) (0)	\$20> 5 11 0 0 (25) (55) (0) (0)
ancreas	atrophy	0 1 0 0 (0) (10) (0) (0)	0 1 0 0 (0) (7) (0) (0)	<12> 0 2 0 0 0 0 (17) (0) (0)	<pre></pre>
	arteritis	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (0)
	islet cell hyperplasia	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 2 0 0 (0) (17) (0) (0)	0 0 0 0 0 (0) (0)
Urinary sy	rstem)				
dney	infarct	0 0 0 0 (0) (0) (0) (0)	<15> 0 0 0 0 0 0 0 0 0 0 0	<12> 0 1 0 0 (0) (8) (0) (0)	<20> 0 0 0 0 0 (0) (0) (0) (0)
	chronic nephropathy	0 2 0 0 (0) (20) (0) (0)	2 6 0 1 (13) (40) (0) (7)	1 3 2 2 (8) (25) (17) (17)	2 10 4 0 * (10) (50) (20) (0)
rade a > b c) ignificant	1: Slight 2: Moderate 3: Marke a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤ 0.01	d 4 : Severe			

(HPT150)

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

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

PAGE: 8

Organ	ı	Group Name Control No. of Animals on Study 10 Grade 1 2 3 4 (%) (%) (%) (%)	25ppm 15 1 2 3 4 (%) (%) (%) (%)	100ppm 12 12 3 4 (%) (%) (%) (%)	400ppm 20 1 2 3 4 (%) (%) (%) (%)
{Urinary syst	cem}				
kidney	mineralization:papilla	1 0 0 0 (10) (0) (0) (0)	<15> 0 0 0 0 0 0 0 0 0 0 0	<12> 1 0 0 0 (8) (0) (0) (0)	<20> 0 0 0 0 0 0 0 0 0 0 0
	mineralization:pelvis	0 1 0 0 (0) (10) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)
urin bladd	simple hyperplasia:transitional epithel	.ium	0 0 0 0 (0) (0) (0) (0)	0 1 0 0 (0) (8) (0) (0)	<20> 0 0 0 0 0 0 0 0 0 0
Endocrine sy	rstem)				
oituitary	hyperplasia	(10) 0 1 0 0 (0) (10) (0) (0)	<15> 0 0 0 0 (0) (0) (0) (0)	<12> 0 1 0 0 (0) (8) (0) (0)	<pre></pre>
thyroid	C-cell hyperplasia	<10> 0 1 0 0 (0) (10) (0) (0)	<15> 0 0 0 0 0 0 0 0 0 0 0 0	<12> 0 1 0 0 (0) (8) (0) (0)	<pre></pre>
adrenal	angiectasis	(10) 0 0 0 0 (0) (0) (0) (0)	<15> 0 1 0 0 (0) (7) (0) (0)	<12> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<20> 0 0 0 0 0 0 0 0 0 0 0

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

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

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

SEX : MALE

Organ	Findings	Group Name Control No. of Animals on Study 10 Grade 1 2 3 4 (%) (%) (%) (%)	25ppm 15 1 2 3 4 (%) (%) (%) (%)	100ppm 12 12 3 4 (%) (%) (%) (%)	400ppm 20 1 2 3 4 (%) (%) (%) (%)
{Reproductiv	ve system)				
testis	atrophy	<10> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<15> 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 (0) (0) (0) (0)	<20> 0 2 0 0 0 0 (10) (0) (0)
	mineralization	0 0 0 0 0 (0) (0)	1 0 0 0 0 (7) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (0)
	arteritis	0 0 0 0 0 (0) (0)	2 1 0 0 (13) (7) (0) (0)	0 1 0 0 (0) (8) (0) (0)	0 0 0 0 0 (0) (0) (0)
	interstitial cell hyperplasia	0 0 0 0 0 (0) (0)	2 2 0 0 (13) (13) (0) (0)	1 1 0 0 (8) (8) (0) (0)	1 3 0 0 (5) (15) (0) (0)
prostate	inflammation	(0) (0) (0) (0) (0) (0) (0) (0)	<15> 0 2 0 0 (0) (13) (0) (0)	0 2 0 0 (0) (17) (0) (0)	<20> 0 1 0 0 (0) (5) (0) (0)
	hyperplasia	0 0 0 0 0 (0) (0)	1 0 1 0	0 0 0 0 0 (0) (0)	1 1 0 0 (5) (5) (0) (0)
{Nervous sys	stem)				
orain	hemorrhage	<10> 0 0 0 0 0 0 0 0 0 0 0	(15) 1 0 0 0 (7) (0) (0) (0)	<12> 0 0 0 0 0 0 0 0 0 0 0	<20> 0 0 0 0 0 0 0 0 0 0 0
Grade (a> b (c)	1: Slight 2: Moderate a: Number of animals examined at the b: Number of animals with lesion c: b/a*100	3 : Marked 4 : Severe site			

(HPT150)

BAIS4

STUDY NO. : 0417 ANIMAL

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

REPORT TYPE : A1 SEX

: MALE

: RAT F344/DuCrj

Organ	Findings	No. of Animals on Study 10 Grade _1 2	ontrol 3 4 (%) (%)	25ppm 15 1 2 3 4 (%) (%) (%) (%)	100ppm 12 12 3 4 (%) (%) (%) (%)	400ppm 20 1 2 3 4 (%) (%) (%) (%)
lervous syst ain	em)	<10> 0 0	0 0	<15> 0 0 0 0	<12>	<20>
	5110010	(0) (0) ((0)(0)(0)(0)	0 0 0 0 (0) (0)	0 1 0 0 (0) (5) (0) (0)
pecial sens	se organs/appendage}					
re	cataract	\(\) 1 0 \(\) 10) (0) (0 0 0 0) (0)	(15) 1 0 0 0 0 (7) (0) (0) (0)	<12> 1 0 0 0 (8) (0) (0) (0)	<20> 0 0 0 0 0 0 0 0 0 0 0
	retinal atrophy	0 0 (0) (0 0 0 0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (8) (0) (0)	0 0 0 0 0
	keratitis	0 0 (0) (0 0 0 0) (0)	0 0 0 0 0 0 (0) (0)	1 0 0 0 0 (8) (0) (0) (0)	0 0 0 0 0
	iritis	0 0 (0) (0 0	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	2 0 0 0 0 (10) (0) (0)
	squamous cell metaplasia:cornea	0 0 (0) (0 0 0 0) (0)	0 0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (5) (0) (0)
solacr d	inflammation	<10> 0 0 (0) (0) (0 0 0 0) (0)	<15> 0 0 0 0 0 0 0 0 0	<12> 0 1 0 0 (0) (8) (0) (0)	<20> 0 0 0 0 0 0 0 0 0 0 0 0 0

(HPT150)

(c)

c:b/a*100

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

BAIS4

SEX : MALE

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

PAGE: 11

Grade	1 2 3 4 (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)
tuscle hemorrhage 0 0 0 0 0 0 0 0 0 0 0 (0) (0) (0)		
hemorrhage		
0 0	0 0 0 0 (0) (0) (0) (0)	<pre></pre>
and 1 Click 2 Valent 2 Valent 4 C	<12> 0 0 0 0 0 0 0 0 0 0 0	<20> 1 0 0 0 (5) (0) (0) (0)
a > a : Number of animals examined at the site b b : Number of animals with lesion c) c : b / a * 100 ignificant difference; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square		

APPENDIX L 3

HISTOPATHOLOGICAL FINDINGS:

NON-NEOPLASTIC LESIONS : SUMMARY,

RAT: MALE:

SACRIFICED ANIMALS

(2-YEAR STUDY)

SEX

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

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (105W)

PAGE: 1

Organ		or Name of Animals on Study de 1 (%)	40 2 (%)	Contro 3 (%)	01 <u>4</u> (%)	1 (%	5)	35 2 (%)	25p 3 (%)	4 (%)	(<u>1</u> %)	38 2 (%)	100pp 3 (%)	0m 4 (%)	<u></u>	L6)	30 2 (%)	400p) 3 (%)	ppm 4 (%)
{Integumenta	ry system/appandage}					***														
skin/app	squamous cell hyperplasia	0 (0)	<40 1 (3) (0	0 (0)	0 (0		<35 1 3) (0	0 (0)		1 3) (<38 0 0) (0 (0	((<30 0 0) (0	0 (0)
	basal cell hyperplasia	0 (0)	1 (3) (0 ()	0 (0)	0 (0		0 (0	0 0)	0 (0)))) (0	0 (0)	0	((0	0	0 (0)
	epidermal cyst	0 (0)	0 (0) (0 0)	0 (0)	0) (1 3) (0 0)	0 (0)	(())) (1 3) (0 (0	((0 (0	0 (0)
(Respiratory	system)																			
asal cavit	eosinophilic change:olfactory epithelium	10 (25)	<40 24 (60) (1	0 (0)	3 (9		<35: 27 77) (4	0 *			<38 31 82) (3 4 (11)	0 ** (0)	5 (17		<30 23 77) (0	0 (0)
	eosinophilic change:respiratory epitheliu		0 (0) (0	0 (0)	1 (3		0 (0 0)	0 (0)	(:	l 3) (0 0) (0 0	0	(0		0	0 (0)	0 (0)
	inflammation:foreign body	3 (8)	11 (28) (0	0 (0)	4 (11		6 17) (0 0)	0 (0)	(1:	1	7 18) (2 5) (0	2 (7		10 33) (0 (0)	0 (0)
	inflammation:respiratory epithelium	0 (0)	0 (0) (0	0	4 (11		2 6) (0 0)	0 *	(13		2 5) (0	0 *	7 (23		10 33) (0 (0)	0 *

b

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

(c)

b: Number of animals with lesion

c:b/a * 100

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

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1 SEX

: MALE PAGE: 2

Organ	Group No. of Grade Findings	Name Control	25ppm 35 1 2 3 4 (%) (%) (%) (%)	100ppm 38 1 2 3 4 (%) (%) (%) (%)	400ppm 30 1 2 3 4 (%) (%) (%) (%)
{Respiratory	system}				
nasal cavit	respiratory metaplasia:olfactory epithelium	<40> 2 1 0 0 (5) (3) (0) (0)	<35> 2 1 0 0 (6) (3) (0) (0)	<38> 0 0 0 0 0 0 0 0 0 0 0	<30> 4 7 0 0 ** (13) (23) (0) (0)
	respiratory metaplasia:gland	10 14 0 0 (25) (35) (0) (0)	11 15 0 0 (31) (43) (0) (0)	10 21 0 0 (26) (55) (0) (0)	2 22 0 0 ** (7) (73) (0) (0)
	squamous cell metaplasia:respiratory epithel	0 0 0 0 0 (0) (0) (0)	1 0 0 0 0 (3) (0) (0)	1 0 0 0 0 (3) (0) (0) (0)	12 3 0 0 ** (40) (10) (0) (0)
	hyperplasia with atypia:transitional epithel	0 0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 3 0 0 (0) (10) (0) (0)
	atrophy:olfactory epithelium	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (3) (0) (0) (0)	10 8 0 0 ** (33) (27) (0) (0)
	necrosis:olfactory epithelium	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	4 1 0 0 * (13) (3) (0) (0)
larynx	inflammation:foreign body	<40> 0 1 0 0 (0) (3) (0) (0)	<35> 0 0 0 0 (0) (0) (0) (0)	<38> 0 0 0 0 0 0 0 0 0 0 0	<30> 0 1 0 0 (0) (3) (0) (0)
trachea	proliferation:histiocyte	<40> 0 1 0 0 (0) (3) (0) (0)	<35> 0 0 0 0 (0) (0) (0) (0)	<38> 0 0 0 0 (0) (0) (0) (0)	<30> 0 0 0 0 (0) (0) (0) (0)

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

(HPT150)

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1 SEX : MALE

PAGE: 3

		Group Name No. of Animals on Study Grade 1	40				3				38					30		
rgan	Findings	Grade <u>1</u> (%)	(%)	(%)	(%)	(%)	(%)	3 4 (%) (%		5)	(%)	(%)	(%)	(1 (%)	(%)	(%)	(%)
Respiratory s	system)																	
ung	bronchiolar—alveolar cell hyperplasia		<40 0 (0) (0	0 (0)	1 (3)	<3! 0 (0)	5> 0 0 (0) (0) (5	; i) (<38 0 0) (0	0 ()		1 3) (<30 0 0)	0> 0 (0)	0 (0)
Hematopoietic	system)																	
one marrow	granulation	1 (3)	<40 0 (0) (0	0 (0)	1 (3)	<3! 0 (0)	5> 0 0 (0) (0)) (<38: 0 0) (0	0 ()		0 0) (<30 0 0) (0 (0)	0 (0)
	increased hematopoiesis	2 (5)	0 (0) (0 0) (0 (0)	0 (0) (0 (0)	0 0			0 0) (0	0 (0)		0 0) (0	0 (0)	0 (0)
	myelofibrosis	0 (0)	0 (0 0) (0 (0)	1 (3) (0 (0)	0 0) (0) (0	0	0 0)		0 0) (0	0 (0)	0 (0)
	granulopoiesis:increased	0 (0)	0 (0) (0	0 (0)	0 (0) (0 0)	0 0) (3) (0 0) (0	0		0 0) (0	0 (0)	0 (0)
mph node	lymphadenitis	0 (0)	<40 0 (0) (0	0 0)	0 (0) (<38 0 0 (0)	0 0 (0) (0)			<382 1 3) (0	0 0)		0 0) (<30 0 0) (0 (0)	0 (0)

(HPT150)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (105W)

PAGE: 4

Organ	Findings	Group Name No. of Animals on Study Grade 1 (%)	Control 40 2 3 4 (%) (%) (%)	25ppm 35 1 2 3 4 (%) (%) (%) (%)	100ppm 38 1 2 3 4 (%) (%) (%) (%)	400ppm 30 1 2 3 4 (%) (%) (%) (%)
{Hematopoiet	ic system}					
splеел	congestion	0 (0)	<40> 0 0 0 (0) (0) (0)	<35> 0 0 0 0 0 0 0 0 0 0 0	<38> 0 1 0 0 0 0) (3) (0) (0)	<30> 0 0 0 0 0 0 0 0 0 0 0
	angiectasis	0 (0)	0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	0 1 0 0 (0) (3) (0) (0)
	deposit of hemosiderin	9 (23)	16 0 0 (40) (0) (0)	6 20 0 0 (17) (57) (0) (0)	4 22 0 0 (11) (58) (0) (0)	6 19 1 0 (20) (63) (3) (0)
	fibrosis	0 (0)	1 0 0 (3) (0) (0)	0 1 0 0 (0) (0)	0 1 0 0 (0) (0) (0)	0 0 0 0 0 (0)
	extramedullary hematopoiesis	0 (0)	1 0 0 (3) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 5 0 0 (0) (13) (0) (0)	0 1 0 0 (0) (0)
Circulatory	system)					
eart	thrombus	0 (0)	<40> 1 0 0 (3) (0) (0)	<35> 0 0 0 0 0 0 0 0 0 0 0	<38> 0 0 0 0 0 0 0 0 0 0	30> 0 0 0 0 (0) (0) (0) (0)
	fibrosis:focal	0 (0)	3 0 0 (8) (0) (0)	0 1 0 0 (0) (3) (0) (0)	0 1 1 0 (0) (3) (3) (0)	1 0 0 0 0 (3) (0) (0) (0)

b

b: Number of animals with lesion

(c) c:b/a*100

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

SEX

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1 : MALE

PAGE: 5

Organ	Findings	Group Name Control No. of Animals on Study 40 Grade 1 2 3 4 (%) (%) (%) (%)	25ppm 35 1 2 3 4 (%) (%) (%) (%)	100ppm 38 1 2 3 4 (%) (%) (%) (%)	400ppm 30 1 2 3 4 (%) (%) (%) (%)
{Circulatory	system)				
heart	myocardial fibrosis	<40> 19 13 0 0 (48) (33) (0) (0)	<35> 8 9 0 0 * (23) (26) (0) (0)	38> 19 6 0 0 (50) (16) (0) (0)	<30> 12 7 0 0 (40) (23) (0) (0)
{Digestive s	ystem)				
tooth	inflammation	<40> 0 1 0 0 (0) (3) (0) (0)	<pre></pre>	<38> 0 0 0 0 0 0 0 0 0 0 0	<30> 1 2 0 0 (3) (7) (0) (0)
ongue	arteritis	<40> 0 2 0 0 (0) (5) (0) (0)	<35> 1 0 0 0 (3) (0) (0) (0)	38> 0 0 0 0 (0) (0) (0) (0)	<30> 1 0 0 0 (3) (0) (0) (0)
tomach	ulcer:forestomach	<40> 0 0 0 0 0 0 0 0 0 0 0	<35> 0 0 0 0 (0) (0) (0) (0)	<38> 1 0 0 0 (3) (0) (0) (0)	<30> 1 0 0 0 (3) (0) (0) (0)
	hyperplasia:forestomach	0 1 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (3) (0) (0) (0)	3 0 0 0 (10) (0) (0) (0)
	erosion:glandular stomach	1 0 0 0 (3) (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	1 0 0 0 0 (3) (0) (0) (0)

b

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

c:b/a * 100

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

(HPT150)

SEX

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

: MALE

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (105W)

PAGE: 6

		Group Name Control No. of Animals on Study 40	25ppm 35	100ppm 38	400ppm 30
Organ	Findings	Grade 1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%)
{Digestive	system}				
liver	herniation	<40> 0 5 0 0 0 0 (13) (0) (0)	<35> 0 4 0 0 (0) (11) (0) (0)	<38> 0 4 0 0 (0) (11) (0) (0)	<30> 0 1 0 0 (0) (3) (0) (0)
	spongiosis	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (3) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	mineralization	0 2 0 0 (0) (5) (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	granulation	0 1 0 0 (0) (3) (0) (0)	0 1 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	inflammatory cell nest	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (3) (0) (0)	0 1 0 0 (0) (3) (0) (0)
	clear cell focus	7 9 0 0 (18) (23) (0) (0)	9 4 0 0 (26) (11) (0) (0)	17 12 0 0 ** (45) (32) (0) (0)	0 6 23 0 ***
	acidophilic cell focus	0 1 0 0 (0) (0)	0 0 0 0 0 (0) (0)	2 1 0 0 (5) (3) (0) (0)	5 9 0 0 *** (17) (30) (0) (0)
	basophilic cell focus	2 1 0 0 (5) (3) (0) (0)	0 1 0 0 (0) (0)	2 5 0 0 (5) (13) (0) (0)	1 5 0 0 (3) (17) (0) (0)

Grade 1 : Slight

2 : Moderate

3 : Marked

4 : Severe

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

b: Number of animals with lesion

c:b/a*100

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

(HPT150)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (105W)

PAGE: 7 Group Name Control 25ppm 100ppm 400ppm No. of Animals on Study 40 35 38 30 Grade Findings_ (%) (%) (%) Organ_ (%) (%) (%) (%) (%) {Digestive system} liver <40> <30> vacuolated cell focus 0 0 0 0 0 0 1 0 0 (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (3)(3)(0)(0) spongiosis hepatis 0 3 (0)(8)(0)(0) (3)(3)(0)(0) (3)(8)(0)(0) (0)(7)(0)(0) bile duct hyperplasia 35 38 0 0 30 0 (0) (100) (0) (0) (0)(100)(0)(0) (0)(100)(0)(0) (0)(100)(0)(0) pancreas <40> <35> ⟨38⟩ <30> atrophy 0 12 0 5 1 0 2 4 0 (8) (13) (0) (0) (3)(34)(0)(0) (3)(13)(3)(0) (7)(13)(0)(0) hyperplasia 0 0 0 0 1 (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(3)(0)(0) arteritis 0 0 0 1 0 (0)(0)(0)(0) (0)(0)(0)(0) (0)(3)(0)(0) (0)(0)(0)(0) islet cell hyperplasia 0 0 0 0 0 0 (0)(5)(0)(0) (0)(3)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) {Urinary system} kidney <40> <35> <38> <30> hyperplasia:tubular epithelial cell 0 0 0 0 0 1 1 0 (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(3)(3)(0)

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

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

c:b/a*100 (c)

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

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : MALE PAGE: 8

Organ	Findings	Group Name Control No. of Animals on Study 40 Grade 1 2 3 4 (%) (%) (%) (%)	25ppm 35 1 2 3 4 (%) (%) (%) (%)	100ppm 38 1 2 3 4 (%) (%) (%) (%)	400ppm 30 1 2 3 4 (%) (%) (%) (%)
					(10) (10) (10)
{Urinary sys	ten}				
kidney	inflammation	<40> 0 0 0 0 (0) (0) (0) (0)	<35> 0 0 0 0 (0) (0) (0) (0)	<38> 0 0 0 0 0 0 0 0 0 0 0	<30> 0 1 0 0 (0) (3) (0) (0)
	inflammatory infiltration	0 0 0 0 0 (0) (0) (0)	0 1 0 0 (0) (3) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	chronic nephropathy	6 26 6 2 (15) (65) (15) (5)	3 29 3 0 (9) (83) (9) (0)	0 24 11 3 (0) (63) (29) (8)	0 18 10 2 (0) (60) (33) (7)
	pyelitis	0 0 0 0 0 (0) (0) (0)	0 1 0 0 (0) (3) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	mineralization:pelvis	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (3) (0) (0)
Endocrine s	ystem)				
pituitary	angiectasis	<40> 0 0 0 0 (0) (0) (0) (0)	<35> 1 0 0 0 (3) (0) (0) (0)	<38> 0 1 0 0 (0) (3) (0) (0)	<30> 0 1 0 0 (0) (3) (0) (0)
	cyst	0 1 0 0 (0) (3) (0) (0)	1 2 0 0 (3) (6) (0) (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)

< a >

a: Number of animals examined at the site

b

b : Number of animals with lesion

(c)

c:b/a*100

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

(HPT150)

BATS4

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : MALE

PAGE: 9

	•	Group Name C No. of Animals on Study 40	ontról	35	25ppm		38	100ppm		9	400pj	pm
rgan	Findings	Grade _1 2	3 4 (%) (%)	1 2	3 4 (%)	(%)	2 (%)	3 4 (%) (%)	(%)	2	3 (%)	(%)
Endocrine s	ystem)											
ituitary	deposit of hemosiderin	(40) 1 0 (3) (0) (0 0 0 0) (0)	0 0 (0) (0) (0 0	0 (0) (<38> 0 0) (0 0 0 0) (0)	0 (0)	(3 0 (0)	0 (0)	0 (0)
	hyperplasia	4 5 (10) (13) (0 0 0 0) (0)	3 4 (9) (11) (0 0	4 (11) (3	0 0 0 0) (0)	2 (7)	1 (3)	0 (0)	0 (0)
	Rathke pouch	0 0 (0) (0 0 0 0) (0)	3 0 (9) (0) (0 0 0 0) (0)	0 (0) (0 0) (0 0 0 0) (0)	0 (0)	0 (0)	0 (0)	0
hyroid	follicular hyperplasia	<40> 0 1 (0) (3) (0 0 0 0) (0)	<35> 0 2 (0) (6) (0 0 0) (0)	(0) (<38> 0 0) (0 0	0 (0)		30> 1 (3)	0
	C-cell hyperplasia	1 3 (3) (8) (3 0	2 4 (6) (11) (1 0 3) (0)	8 (21) (1 3) (0 0 *	1 (3)	3 (10)	0 (0)	0
adrenal	hyperplasia:cortical cell	<40> 0 0 (0) (0) (0 0	(35> 0 0 (0)(0)(0 0 0) (0)	0 (0) (<38> 0 0) (0 0 0) (0)	1 (3)		0 (0)	0 (0)
	hyperplasia:medulla	0 5 (0) (13) (0 0	1 1 (3) (3) (0 0	1 (3) (2 5) (0 0 0 0) (0)	2 (7)	3 (10)	0 (0)	0 (0)

(c) c:b/a*100

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

(HPT150)

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

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

SACRIFICED ANIMALS (105W)

PAGE: 10

		No. of Animals on Study 40	ntrol	25ppm 35		100ppm 38	400ppm 30
rgan	Findings	Grade 1 2 3 (%) (%) (%)	3 <u>4</u> <u>1</u> (%)	2 3 4 (%) (%) (%)	<u>I 2</u> (%) (%		1 2 3 4 (%) (%) (%) (%)
Reproductive	system)						
estis	atrophy	<40> 0 2 0 (0) (5) (0		<35> 2 0 0 (6) (0) (0)	0 1	(38> 0 0) (0) (0)	<30> 0 0 0 0 (0) (0) (0) (0)
	mineralization	0 0 0	0 0 0	0 0 0 0 (0) (0)	0 1	0 0	0 0 0 0 0 0 (0) (0)
	arteritis	1 2 0	0 1 (3) (1 0 0 (3) (0) (0)	0 3	0 0	0 0 0 0 0 0 (0) (0)
	interstitial cell hyperplasia	6 3 0 (15) (8) (0	0 6 6 (17) (3 0 0 (9) (0) (0)	8 1 (21) (3	0 0	2 1 0 0 (7) (3) (0) (0)
ostate	inflammation	(40) 0 0 0 (0) (0) (0	0 0 0	<35> 0 0 0 (0) (0) (0)	0 0	(38) 0 0 0 (0) (0)	<pre></pre>
	hyperplasia	1 2 2 (3) (5) (5	3 0 2 5) (0) (6) (4 1 0 (11) (3) (0)	3 2 (8) (5	1 0	4 5 1 0 (13) (17) (3) (0)
rep/cli gl	duct ectasia	<40> 0 1 0 (0) (3) (0		<35> 0 0 0 (0) (0) (0)	0 1	(38> 0 0 0 (0) (0)	<30> 0 0 0 0 (0) (0) (0) (0)

(HPT150)

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

ANIMAL : RAT F344/DuCrj

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (105W)

REPORT TYPE : A1 SEX : MALE

PAGE: 11

)rgan	Findings	Group Name No. of Animals on Study Grade(%)	Control 40 2 3 4 (%) (%) (%)	25ppm 35 1 2 3 4 (%) (%) (%) (%)	100ppm 38 1 2 3 4 (%) (%) (%) (%)	400ppm 30 1 2 3 4 (%) (%) (%) (%)
Nervous syst	tem}					
ain	angiectasis	0 (0)	<40> 0 0 0 (0) (0) (0)	<35> 0 0 0 0 (0) (0) (0) (0)	<38> 0 1 0 0 (0) (3) (0) (0)	<pre></pre>
pecial sens	se organs/appendage)					
e	cataract	2 (5)	<40> 0 0 0 (0) (0) (0)	<35> 3 0 0 0 (9) (0) (0) (0)	<38> 5 0 0 0 (13) (0) (0) (0)	<30> 1 0 0 0 (3) (0) (0) (0)
	retinal atrophy	2 (5)	0 0 0 0 (0) (0)	2 1 0 0 (6) (3) (0) (0)	0 5 0 0 * (0) (13) (0) (0)	0 2 0 0 (0) (7) (0) (0)
	keratitis	0 (0)	0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0	1 0 0 0 0 (3) (0) (0)
	squamous cell metaplasia:cornea	0 (0)	0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (3) (0) (0)	0 0 0 0 0 (0) (0)
solacr d	squamous cell metaplasia	0 (0)	<40> 0 0 0 (0) (0) (0)	<35> 0 0 0 0 0 0 0 0 0 0 0	<38> 0 0 0 0 0 0 0 0 0 0 0	<30> 0 1 0 0 (0) (3) (0) (0)
ade a > b c) gnificant d	1: Slight 2: Moderate a: Number of animals examined at th b: Number of animals with lesion c: b/a*100 difference; *: P ≤ 0.05 **:	$3: Marked$ $4: Severe$ e site $P \leq 0.01$ Test of Chi Squar				

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : MALE

PAGE: 12

		Group Name No. of Anima	s on Stu	ıdy	40	Contr 0	rol			35	25p	pm			3	100p 8	pm			9	400 0	ppm	
{Body cavities} adipose Grade 1 <a>a>a a	Findings	Grade		(%)	(%)	(%)	(%)	(<u>(</u>	(%)	(%)	(%)	i	<u>1</u> (%)	(%)	3 (%)	(%)	•	1 (%)	2 (%)	(%)	((%)
Body cavities)																							
dipose	granulation			0	<40 1 (3)	0> 0 (0)	0 (0)))) (<35> 0 0) (0 0)	0 (0)		0 0) (<30 0 0)	8> 0 (0)	0 (0)	(0 0) (0	0 (0)	(0 0)
(a) a b b (c) c	: Slight 2: Moderate a: Number of animals examined b: Number of animals with les c: b / a * 100 Cference; *: P ≤ 0.05	at the site ion		Severe														-					

APPENDIX L 4

HISTOPATHOLOGICAL FINDINGS:

NON-NEOPLASTIC LESIONS : SUMMARY,

RAT: FEMALE:

ALL ANIMALS

(2-YEAR STUDY)

SEX

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

: FEMALE

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

PAGE: 16

Organ		Group Name Cont No. of Animals on Study 50 Grade 1 2 3 (%) (%) (%)	411	25ppm 50 2 3 4 (%) (%) (%)	100ppm 50 1 2 3 4 (%) (%) (%) (%)	400ppm 50 1 2 3 4 (%) (%) (%) (%)
{Integumentar	y system/appandage)					
skin/app	inflammation	<50> 0 2 0 (0) (4) (0)	0 0 (0) (<50> 0 0 0 0) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)
	epidermal cyst	0 0 0 (0) (0)	0 0 (0) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 (0) (0)	0 2 0 0 (0) (4) (0) (0)
{Respiratory	system)					
nasal cavit	mineralization	3 0 0 (6) (0) (0)		<50> 0 0 0 0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
	eosinophilic change:olfactory epitheli	um 3 33 12 (6) (66) (24)	0 0 (0) (27 23 0 * 54) (46) (0)	1 32 17 0 (2) (64) (34) (0)	1 43 3 0 * (2) (86) (6) (0)
	eosinophilic change:respiratory epithe	1ium 0 0 0 0 (0) (0)	0 3 (6) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	6 0 0 0 * (12) (0) (0) (0)	0 0 0 0 0 0 (0) (0)
	inflammation:foreign body	1 1 0 (2) (2) (0)	0 1 (2) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	2 0 0 0 0 (4) (0) (0) (0)	2 1 0 0 (4) (2) (0) (0)
	inflammation:respiratory epithelium	0 0 0 0 (0) (0)	0 3 (6) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	4 0 0 0 0 (8) (0) (0) (0)	12 1 0 0 ** (24) (2) (0) (0)

Grade 1 : Slight

2 : Moderate

3 : Marked

4 : Severe

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

b : Number of animals with lesion

c:b/a*100

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

(HPT150)

: RAT F344/DuCrj

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

REPORT TYPE : A1 SEX : FEMALE

ANIMAL

PAGE: 17

		roup Name o. of Animals on Study	50	Contr	ol			25p 30	pm			50	100pp	om				400рр	an .
Organ		rade (%)	2 (%)	3 (%)	(%)	(%)	2 (%)	(%)	<u>4</u> (%)	<u>1</u> (%		2 (%)	3 (%)	(%)	<u>1</u> (%)	2) (%		3 (%)	<u>4</u> (%)
{Respiratory	system)																		
nasal cavit	respiratory metaplasia:olfactory epithe		<500 0 (0) (0	0 (0)	1 (2)	0	(0) (0)	0 (0)	0 (0		<50 0 0) () 0 0) (0	0 (0)			0	0
	respiratory metaplasia:gland	17 (34)	15 (30) (0	0	22 (44)	16 (32)	0 (0)	0 (0)	25 (50		.8 36) (0	0 * (0)	3 (6)	30) (60		0 (0 ** 0)
	squamous cell metaplasia:respiratory ep		0 (0) (0	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	2 (4) (0 0) (0	0	16 (32)	9) (18) (0 (0 ** 0)
	hyperplasia with atypia:transitional ep		0 (0) (0 0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0		1 2) (0	0	1 (2)	1 (2		0 (0
	atrophy:olfactory epithelium	0 (0)	0 (0) (0 0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0		0 0) (0	0	21 (42)	16) (32		2 4) (0 ** 0)
	necrosis:olfactory epithelium	0 (0)	0 (0) (0 0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0		0 0) (0.	0 (0)	8 (16)	0		0 (0 ** 0)
lung	inflammatory infiltration	0 (0)	<50) 1 (2) (0	0	0 (0)	0	0 (0)	0 (0)	0 (0) (<502 1 2) () 0 0) (0 (0)	1 (2)	1		0 (0 0)
	bronchiolar-alveolar cell hyperplasia	1 (2)	0 (0) (0 0)	0	0 (0)	0 (0)	0 (0)	0 (0)	2 (4		0 0) (0	0 (0)	0 (0)	0 (0)		0 0) (0 0)

Grade 1 : Slight 2 : Moderate

3 : Marked

4 : Severe

< a >

a: Number of animals examined at the site

b (c) b: Number of animals with lesion

c:b/a*100

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

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE

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

PAGE: 18

		Group Name No. of Animals on Study Grade 1	Control 50 2 3 4	25ppm 50 1 2 3 4	100ppm 50 _1 _2 3 4	400ppm 50 1 2 3 4
rgan	Findings	(%)	(%) (%) (%)	(%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)
Hematopoiet	ic system)					
one marrow	granulation	5 (10)	<50> 0 0 0 (0) (0) (0)	50> 5 1 0 0 (10) (2) (0) (0)	2 0 0 0 (4) (0) (0) (0)	<50> 2 1 0 0 (4) (2) (0) (0)
	histiocytosis	1 (2)	0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0) (0)
	increased hematopoiesis	(4)	0 0 0 0 (0) (0)	3 0 0 0 0 (6) (6) (7)	2 0 0 0 0 (4) (0) (0) (0)	11 0 0 0 ** (22) (0) (0) (0)
pleen	deposit of hemosiderin	2 (4)	<50> 38 4 0 (76) (8) (0)	<50> 1 43 1 0 (2) (86) (2) (0)	(50) 1 38 2 0 (2) (76) (4) (0)	<50> 1 28 0 0 \$\frac{1}{2}\$ (56) (0) (0)
	fibrosis:focal	0 (0)	0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0 (0) (0)
	extramedullary hematopoiesis	0 (0)	4 1 0 (8) (2) (0)	0 3 0 0	0 5 2 0 (0) (10) (4) (0)	0 9 3 0 (0) (18) (6) (0)
Circulatory	system)					
eart	thrombus	1 (2)	<50> 0 0 0 (0) (0) (0)	<50> 0 0 0 0 0 0 0 0 0 0 0	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)

< a >

a : Number of animals examined at the site

b

b: Number of animals with lesion

(c)

c:b/a * 100

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

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1
SEX : FEMALE

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

PAGE: 19

Organ	No	roup Name	25ppm 50 1 2 3 4 (%) (%) (%) (%)	100ppm 50 1 2 3 4 (%) (%) (%) (%)	400ppm 50 1 2 3 4 (%) (%) (%) (%)
{Circulato	ry system}				
eart	inflammatory infiltration	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
	fibrosis:focal	0 0 0 0 0 (0) (0)	1 1 0 0 (0) (2) (2) (0) (0)	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0 (0) (0)
	myocardial fibrosis	7 0 0 0 (14) (0) (0) (0)	11 0 0 0 (22) (0) (0) (0)	13 3 0 0 (26) (6) (0) (0)	11 0 0 0 (22) (0) (0) (0)
)igestive	system}				
ooth	inflammation	(50) 0 0 0 0 (0) (0) (0) (0)	(50) 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)
ongue	inflammation	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>
	squamous cell hyperplasia	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 2 0 0 (0) (4) (0) (0)	1 1 0 0 (2) (2) (0) (0)
rade a > b c) ignifican	1: Slight 2: Moderate 3: a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 t difference; *: P ≤ 0.05 **: P ≤ 0				

(HPT150)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1
SEX : FEMALE

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

PAGE: 20

Organ	Findings	Group Name	50 2	3 4 (%) (%)	1 (%)	50 2 (%)	25pp) 3 (%)	om 4 (%)	<u>1</u> (%)	50 2 (%)	100pp 3 (%)	om 4 (%)	(<u>1</u> (%)	5(2 (%)	400p) 3 (%)	9pm 4 (%)
{Digestive :	system}																
tongue	arteritis	0 (0)	<50> 0 (0) (0 0 0 0) (0)	0 (0)	<50 0 (0)	0	0 (0)	1 (2) (<50 0 (0)	0	0 (0)		0 0) (<50 0 0)	0	0 (0)
stomach	basal cell hyperplasia	0 (0)		0 0 0 0) (0)	0 (0)	<50 0 (0)	0	0 (0)	1 (2) (<50 0 0	0	0 (0)		0 0) (<50 0 0)	0	0 (0)
	ulcer:forestomach	0 (0)	2 (4) (0 0 0 0) (0)	0 (0)	0 (0)	0 (0) (0 (0)	1 (2) (1 2)	0	0 (0)	(1 2) (1 2)	0 (0)	0 (0)
	hyperplasia:forestomach	0 (0)	1 (2) (0 0 0 0) (0)	0 (0)	0 (0)	0 (0) (0 (0)	0 (0) (0 0)	0 (0)	0 (0)	(0 0) (1 2)	0 (0)	0 (0)
	inflammation:forestomach	0 (0)	0 (0) (0 0 0 0) (0)	0 (0)	1 (2)	0 (0) (0 (0)	0 (0) (0	0	0 (0)		0 0) (0	0 (0)	0 (0)
	erosion:glandular stomach	1 (2)		0 0 0 0) (0)	0 (0)	0 (0)	0 (0) (0 (0)	1 (2) (0 0)	0	0 (0)	(1 2) (0	0 (0)	0 (0)
	ulcer:glandular stomach	0 (0)	0 (0) (0 0 0) (0)	0 (0)	0 (0)	0 (0	0 (0) (0 0)	0	0	(2 4) (0	0 (0)	0 (0)
	hyperplasia:glandular stomach	0 (0)	0 (0) (0 0 0 0) (0)	0 (0)	1 (2)	0 (0) (0 (0)	0 (0) (0 0)	0 (0) (0 (0)		0 0) (0	0 (0)	0 (0)

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

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

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

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

SEX

ANIMAL : RAT F344/DuCrj

: FEMALE

REPORT TYPE : A1

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

PAGE: 21

Organ	Findings	Group Name No. of Animals on Study Grade 1 (%)	Control 50 2 3 4 (%) (%) (%)	25ppm 50 1 2 3 4 (%) (%) (%) (%)	100ppm 50 1 2 3 4 (%) (%) (%) (%)	400ppm 50 1 2 3 4 (%) (%) (%) (%)
{Digestive sys	stem}					
stomach	inflammation:glandular stomach	0 (0) (<50> 0 0 0 (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)
small intes	hyperplasia	0 (0) (<50> 0 0 0 (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 0 0 0 0 0 0	<50> 0 1 0 0 (0) (2) (0) (0)
liver	herniation	0 (0) (<50> 9 0 0 (18) (0) (0)	<50> 0 9 0 0 (0) (18) (0) (0)	<50> 0 10 0 0 (0) (20) (0) (0)	<50> 0 6 0 0 (0) (12) (0) (0)
	necrosis:central	0 (0) (0 0 0 0 (0) (0)	0 1 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)
	fatty change	0 (0) (0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 1 0 (0) (2) (0)	0 0 0 0 0 (0) (0)
	fatty change:central	0 (0) (1 0 0 (2) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	granulation		13 1 0 (26) (2) (0)	5 5 0 0 (10) (10) (0) (0)	0 3 0 0 ** (0) (6) (0) (0)	1 2 0 0 *** (2) (4) (0) (0)

Grade

1 : Slight

2 : Moderate

3 : Marked

4 : Severe

< a >

a: Number of animals examined at the site

b

b: Number of animals with lesion

(c)

c:b/a * 100

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

(HPT150)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1
SEX : FEMALE

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

PAGE: 22

Organ	. Findings	Group Name No. of Animals on Study Grade 1 (%)	Control 50 2 3 4 (%) (%) (%)	25ppm 50 1 2 3 4 (%) (%) (%) (%)	100ppm 50 1 2 3 4 (%) (%) (%)	400ppm 50 1 2 3 4 (%) (%) (%) (%)
{Digestive	system)					
liver	inflammatory cell nest	0 (0) (<50> 2	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)
	clear cell focus	3 (6) (1 0 0 2) (0) (0)	0 0 0 0 0 (0) (0) (0)	7 0 0 0 (14) (0) (0) (0)	1 12 20 1 ** (2) (24) (40) (2)
	acidophilic cell focus	0 (0) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0)	4 9 0 0 ***
	basophilic cell focus	15 (30) (8 0 0 16) (0) (0)	9 5 0 0 (18) (10) (0) (0)	11 9 0 0 (22) (18) (0) (0)	1 5 0 0 ** (2) (10) (0) (0)
	bile duct hyperplasia	(2) (3 0 0 6) (0) (0)	4 7 0 0 (8) (14) (0) (0)	17 12 0 0 ** (34) (24) (0) (0)	13 9 0 0 ** (26) (18) (0) (0)
	biliary cyst	0 (0) (1 0 0 2) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)
pancreas	atrophy	(2) (<50> 3	<50> 1 5 0 0 (2) (10) (0) (0)	<50> 0 2 0 0 0 0 (4) (0) (0)	<50> 0 2 0 0 (0) (4) (0) (0)
	hyperplasia	0 (0) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)

Grade 1: Slight
<a>a a: Number of an

a : Number of animals examined at the site

3 : Marked

4 : Severe

2 : Moderate

b b: Number of animals with lesion

(c) c:b/a*100

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

(HPT150)

: RAT F344/DuCrj

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

ANIMAL REPORT TYPE : A1

SEX

: FEMALE

PAGE: 23

		Group Name No. of Animals on Study	Contr 50	ol		50	25ррт		5	100p;	pm			40 50	Oppm	
Organ	Findings	Grade <u>1</u> (%)	2 3 (%) (%)	(%)	(%)		3 <u>4</u> %) (%)	(%)	2 (%)	(%)	(%)	<u>1</u> (%)) (%	. 3		<u>4</u> %)
{Urinary sys	tem)															
kidney	hyperplasia:tubular epithelial cell	0 (0)	<50> 0 0 (0) (0)	0 (0)	0 (0) (<50> 0 0) (0 0	0 (0)	1	0> 0 (0)	0 (0)	0 (0)	2	<50> 0		0 0)
	deposit of hemosiderin	0 (0)	0 0	0 (0)	0 (0) (0 0 0) (0)	0 (0)	0 (0)	0 (0)	0 (0)	(0)		; 0 :) (0		0 0)
	chronic nephropathy	20 (40)	2 0 (4) (0)	0 (0)	11 1 (22) (2	2 4) (1 0 * 2) (0)	19 (38)	17 (34)	1 (2)	1 ** (2)	9 (18)		5 (10		0 ** 0)
	tubular necrosis	0 (0)	1 0 (2) (0)	0 (0)	0 (0) (0 0) (0 0 0) (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)		0		0 0)
	mineralization:papilla	0 (0)	2 0 (4) (0)	0 (0)	0 (0) (4 8) (0 0 0) (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	1) (2	. 0		0 0)
	mineralization:pelvis	0 (0)	0 0 (0)	0 (0)	0 (0) (1 (0 0	0 (0)	2 (4)	0 (0)	0 (0)	0 (0)		. 0		0 0)
	glomerulosclerosis	0 (0)	1 0 (2) (0)	0 (0)	0 (0) (0) (0 0 0) (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)		. 0) (0		0 0)
{Endocrine s	ystem}															
pituitary	angiectasis	1 (2)	<50> 4 0 (8) (0)	0 (0)	3 (6) (0 0 0) (0)	3 (6)	1		0 (0)	0 (0)	3	<50> 0) (0		0 0)

2 : Moderate

3 : Marked

Grade

1 : Slight

4 : Severe

< a >

a : Number of animals examined at the site

b

b : Number of animals with lesion

c:b/a * 100 (c)

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

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : FEMALE PAGE: 24

Organ	Findings	No. of Animals on Study 50 Grade 1 2	3 4 1 (%)	25ppm 50 2 3 4 (%) (%) (%)	100ppm 50 1 2 3 4 (%) (%) (%)	400ppm 50 1 2 3 4 (%) (%) (%) (%)
{Endocrine sy	ystem)					
pituitary	cyst	<50> 2 2 (4) (4) (0 0 1 0 (2) (<50> 1	<50> 1 1 0 0 (2) (2) (0) (0)	\(\langle 50 \rangle \) \[1 2 0 0 \\ (2) (4) (0) (0) \]
	hyperplasia	2 8 (4) (16) (0 0 3 0 (6) (12 0 0 24) (0) (0)	4 5 0 0 (8) (10) (0) (0)	4 4 0 0 (8) (8) (0) (0)
	Rathke pouch	0 0 (0) (0 0 1 0) (0) (2) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
thyroid	cyst	<50> 0 0 (0) (0) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<50> 0	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)
	ultimibranchial body remanet	0 1 (0) (2) (0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	follicular hyperplasia	0 0 (0) (0 0 0 0	1 0 0 2) (0) (0)	1 0 0 0 0 (2) (0) (0)	0 1 0 0 (0) (0)
	C-cell hyperplasia	4 3 (8) (6) (0 0 10 0) (20) (6 0 0 12) (0) (0)	7 4 0 0 (14) (8) (0) (0)	2 3 0 0 (4) (6) (0) (0)
adrenal	peliosis-like lesion	<50> 2 1 (4) (2) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<50> 0	<50> 0 1 0 0 (0) (2) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)

Grade 1 : Slight 2 : Moderate

3 : Marked

4 : Severe

< a > b

a : Number of animals examined at the site

b: Number of animals with lesion (c)

c:b/a * 100

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

(HPT150)

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1 SEX : FEMALE

PAGE: 25

		Group Name No. of Animals on Study	5	Conti	rol			50	25p	om			5	100r	pm			50	400p	mqç
rgan	Findings	Grade 1 (%)	2 (%)	(%)	(%)	1)	2 (%)	3 (%)	<u>4</u> (%)	-	<u>1</u> (%)	2 (%)	3 (%)	(%)		(%)	(%)	3 (%)	4 (%
Endocrine sy	rstem}																			
drenal	hyperplasia:medulla	2 (4)	<5 0 (0)	0	0 (0)	0 (0)) (<50 0 0) (0 0)	0 (0)	(1 2) (<50 0 0)	0	0 (0)	(1 2) (<50 0 (0)	0 (0)	(0
	focal fatty change:cortex	0 (0)	1 (2)	0 (0)	0 (0)	2 (4) (3 6) (0	0 (0)	(0 0) (1 2)	0 (0)	0 (0)	(1 2) (2 (4)	0 (0)	(0
Reproductive	system)																			
ary	cyst	0 (0)	<5 0 (0)	0	0 (0)	0 (0) (<50 0 0) (0	0 (0)	(0 0) ((5) 1 2)		0 (0)	(0 0) (<5: 1 (2)		0)
erus	blood retention	1 (2)	<5 0 (0)	0	0 (0)	0 (0) (<50 0 0) () 0 0)	0 (0)	(0 0) (<50 0 0)	0	0 (0)	(0 0) (0	0 (0)	((
	cystic endometrial hyperplasia	2 (4)	3 (6)	0 (0)	0 (0)	3 (6		1 2) (0 0)	0	(2 4) (0	0 (0)	0 (0)	(6 12) (1 (2)	0 (0)	(0
agina	blood retention	0 (0)	<5 1 (2)	0	0 (0)	0 (0)) (<50 0 0) (0	0	(0	<5 0 0)	0	0 (0)	(0	<5: 0 (0)	0 (0)	((

(c)

c:b/a*100

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

(HPT150)

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

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

PAGE: 26

Organ	Group No. of Grade Findings	Name Control Animals on Study 50 1 2 3 4 (%) (%) (%) (%)	25ppm 50 1 2 3 4 (%) (%) (%) (%)	100ppm 50 1 2 3 4 (%) (%) (%) (%)	400ppm 50 1 2 3 4 (%) (%) (%) (%)
{Reproductive	system)				
prep/cli gl	duct ectasia	<50> 0 1 0 0 (0) (2) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 1 0 0 (0) (2) (0) (0)
{Nervous syst	em}				
brain	gliosis	<50> 0 0 0 0 (0) (0) (0) (0)	(50) 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
spinal cord	hemorrhage	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 0 (0) (0) (0) (0)
	gliosis	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0)	1 0 0 0 0 (2) (0) (0) (0)	0 0 0 0 0 (0) (0)
{Special sens	e organs/appendage}			•	
еуе	cataract	<50> 2 0 0 0 (4) (0) (0) (0)	50> 5 0 0 0 (10) (0) (0) (0)	<50> 2 0 0 0 (4) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)
Grade <a> b (c) Significant d	1: Slight 2: Moderate 3: Mark a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 ifference; *: P ≤ 0.05 **: P ≤ 0.01	ed 4: Severe Test of Chi Square			

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

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

PAGE: 27

Organ	Findings	Group Name	Control 50 3 4 (%) (%)	25ppm 50 1 2 3 4 (%) (%) (%) (%)	100ppm 50 1 2 3 4 (%) (%) (%) (%)	400ppm 50 1 2 3 4 (%) (%) (%)
{Special sens	e organs/appendage)					
эуе	retinal atrophy	0 2	0 0 (0) (0)	<50> 0 5 0 0 (0) (10) (0) (0)	<50> 0 2 0 0 (0) (4) (0) (0)	<50> 1 1 0 0 (2) (2) (0) (0)
	iritis	0 1	0 0 (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (2) (0) (0)	0 0 0 0 0 (0) (0) (0)
	squamous cell metaplasia:cornea	0 0	0 0 (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	2 0 0 0 0 (4) (0) (0) (0)
arder gl	inflammation	0 0	0 0 (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)	<50> 1 0 0 0 (2) (0) (0) (0)	<50> 0 0 0 0 (0) (0) (0) (0)
nasolacr d	inflammation	2 5	0 0 (0) (0)	<50> 1 3 0 0 (2) (6) (0) (0)	<50> 1 1 0 0 (2) (2) (0) (0)	(50) 0 1 0 0 (0) (2) (0) (0)
{Musculoskele	tal system)					
oone	osteosclerosis	4 0	50> 0 0 (0) (0)	3 0 0 0 (6) (0) (0) (0)	3 3 1 0 (6) (6) (2) (0)	2 0 0 0 (4) (0) (0) (0)

(HPT150)

(c)

c:b/a*100

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

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : FEMALE

PAGE: 28

		Group Name No. of Anim	als on Stud	y	50	Contro	ol			29 50	ppm			100 50	ppm			50	400pp	m
rgan	Findings	Grade		(%)	(%)	3 (%)	(%)	<u>1</u> (%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	1 (%	() !	2 (%)	3 (%)	(%)
Body cavities)																			
eritoneum	inflammation			0	<501	0	0	0	0	50>	0	0	0	50>	0	C)	<50: 0	> 0	0
			(0) (2) (0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0		0) ((0)
a > b c)	1: Slight 2: Moderate a: Number of animals examined a b: Number of animals with lesio c: b/a * 100 fference; *: P \leq 0.05 *	on	4 : Se																	

APPENDIX L 5

HISTOPATHOLOGICAL FINDINGS:

NON-NEOPLASTIC LESIONS : SUMMARY,

RAT: FEMALE:

DEAD AND MORIBUND ANIMALS

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY) DEAD AND MORIBUND ANIMALS (0-105W)

REPORT TYPE : A1

SEX

: FEMALE

PAGE: 12

Organ		•	Control 12 3 4 (%) (%)	25ppm 5 1 2 3 4 (%) (%) (%) (%)	100ppm 11 1 2 3 4 (%) (%) (%) (%)	400ppm 24 1 2 3 4 (%) (%) (%) (%)
					(10) (10) (10)	
{Integumentar	ry system/appandage)					
kin/app	epidermal cyst	0 0	0 0 (0) (0)	< 5> 0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	<24> 0 1 0 0 0 0 (4) (0) (0)
Respiratory	system)					
asal cavit	eosinophilic change:olfactory epithelium	2 8	(12> 1 0 (8) (0)	<pre></pre>	<11> 1 7 3 0 (9) (64) (27) (0)	<24> 1 20 1 0 (4) (83) (4) (0)
	inflammation:foreign body	0 0 (0) (0)	0 0 (0)	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	1 0 0 0 0 (4) (0) (0)
	inflammation:respiratory epithelium	0 0	0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	6 1 0 0 (25) (4) (0) (0)
	respiratory metaplasia:gland	7 0 (58) (0)	0 0 (0)	3 0 0 0 (60) (0) (0) (0)	4 5 0 0 * (36) (45) (0) (0)	1 15 0 0 * (4) (63) (0) (0)
	squamous cell metaplasia:respiratory epit		0 0 (0) (0)	0 0 0 0 0 (0) (0)	2 0 0 0 0 (18) (0) (0) (0)	9 5 0 0 * (38) (21) (0) (0)
	atrophy olfactory epithelium	0 0	0 0	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	3 9 2 0 * (13) (38) (8) (0)

b : Number of animals with lesion

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

(HPT150)

ANIMAL : RAT F344/DuCrj

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

DEAD AND MORIBUND ANIMALS (0-105W)

PAGE: 13

Organ	No.	oup Name Control of Animals on Study 12 ade 1 2 3 4 (%) (%) (%) (%)	25ppm 5 1 2 3 4 (%) (%) (%) (%)	100ppm 11 1 2 3 4 (%) (%) (%) (%)	400ppm 24 1 2 3 4 (%) (%) (%) (%)
{Respiratory	system}				
asal cavit	necrosis:olfactory epithelium	<12> 0 0 0 0 0 0 0 0 0 0 0	(0) (0) (0) (0) (0)	<11> 0 0 0 0 0 0 0 0 0 0 0 0	3 0 0 0 (13) (0) (0) (0)
ung	inflammatory infiltration	0 1 0 0 (0) (8) (0) (0)	<pre></pre>	<11> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	(24) 1 1 0 0 (4) (4) (0) (0)
Hematopoieti	c system}				
one marrow	granulation	<12> 0 0 0 0 (0) (0) (0) (0)	< 5> 1 0 0 0 (20) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	1 0 0 0 (4) (0) (0) (0)
	increased hematopoiesis	2 0 0 0 (17) (0) (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (9) (0) (0)	7 0 0 0 (29) (0) (0) (0)
oleen	deposit of hemosiderin	1 6 2 0 (8) (50) (17) (0)	< 5> 0 3 1 0 (0) (60) (20) (0)	<11> 0 6 0 0 (0) (55) (0) (0)	(24) 1 11 0 0 (4) (46) (0) (0)
	extramedullary hematopoiesis	0 0 1 0 (0) (8) (0)	0 0 0 0 0	0 2 1 0 (0) (18) (9) (0)	0 7 2 0 (0) (29) (8) (0)
a > b c)	1: Slight 2: Moderate 3: Note a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 ifference; $*: P \le 0.05$ **: $*: P \le 0.05$	arked 4: Severe 01 Test of Chi Square			

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

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

PAGE: 14

Organ	Findings	Group Name No. of Animals on Study Grade 1 (%)	12 2 (%)	Contro 3 (%)	4 (%)	1(%)	2 (%)	25p 5 3 (%)	9pm 4 (%)	<u>1</u> (%	<u>(</u>	2 (%)	100p	9pm 4 (%)	1 (%)		24 2	100ppm 3 (%)	n 4 (%)
{Circulator	y system)										-								
heart	thrombus	1 (8)	<12: 0 (0) (0	0 ()	0 (0)	(0)	0	0 (0)	0 (0))) (<11 0 0) (0 (0)	0 (0)	0 (0)		<24>))) (0 0) (0
	myocardial fibrosis	1 (8)	0 (0) (0	0 0)	1 (20)	0 (0)	0 (0)	0 (0)	2 (18		1 9) (0 (0)	0 (0)	4 (17)	0)))) (0	0
{Digestive :	system)																		
stomach	ulcer:forestomach	0 (0)	<12: 2 (17) (0	0 0)	0 (0)	0 (0)	0	0 (0)	1 (9	i) (<11 1 9) (0 (0)	0 (0)	1 (4)	1	<24>	0 0) (0
	hyperplasia:forestomach	0 (0)	0 (0) (0	0 0)	0 (0)	0 (0)	0 (0)	0 (0)	0		0	0 (0)	0 (0)	0 (0)	1 (4	()	0 0) (0
	inflammation:forestomach	0 (0)	0 (0) (0	0	0 (0)	1 (20)	0 (0)	0 (0)	0) (0	0 (0)	0 (0)	0 (0)	0 (0)) (0 0) (0
	erosion:glandular stomach	1 (8)	0 (0) (0	0 0)	0 (0)	0 (0)	0 (0)	0 (0)	0) (0	0 0)	0 (0)	0 (0)	0) (0 0) (0
	ulcer:glandular stomach	0 (0)	0 (0) (0	0	0 (0)	0 .	0 (0)	0 (0)	0 (0		0	0 (0)	0 (0)	1 (4)	0 (0) (0 0) (0

< a >

b

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

(c) c:b/a*100

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

ANIMAL

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

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

PAGE: 15

Organ	Findings	Group Name No. of Animals on Study Grade	12 (%)	3	4 (%)	<u>1</u> (%)	2 (%)	25pp 5 3 (%)	9m 4 (%)	<u>1</u> (%)	2 (%)	100p 11 3 (%)	4 (%)	- (1 (%)	24 2 (%)	400p 4 3 (%)	4 (%)
{Digestive sy	stem)																	
small intes	hyperplasia	0 (0)	<12: 0 (0) (0	0 0)	0 (0)	(0)	0	0 (0)	0 (0)	0	0 (0)	0 (0)	(0 0) (<24 1 4) (1> 0 (0)	0 (0)
liver	herniation	0 (0)	<123 2 (17) (0	0 0)	0 (0)	() 1 (20)	0	0 (0)	0 (0)	1.	0 (0)	0 (0)	(0 0) (<24 3 13) (1> 0 (0)	0 (0)
	necrosis:central	0 (0)	0 (0) (0 (0 0)	0 (0)	0 (0)	0 (0) (0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	(0	1 4) (0	0 (0)
	fatty change	0 (0)	0 (0) (0 0) (0 0)	0 (0)	0 (0)	0 (0) (0 ()	0 (0)	0 (0)	1 (9)	0 (0)	(0 0) (0	0	0 (0)
	fatty change:central	0 (0)	1 (8) (0	0 0)	0 (0)	0 (0)	0 (0) (0 ()	0 (0)	0 (0)	0 (0)	0 (0)		0 0) (0	0	0 (0)
	granulation	0 (0)	2 (17) (0	0 0)	0 (0)	0 (0)	0 (0) (0 0)	0 (0)	2 (18)	0 (0)	0 (0)	(0 0) (0 0) (0	0 (0)
	inflammatory cell nest	0 (0)	0 (0) (0 (0	0 0)	0 (0)	0 (0)	0 (0) (0 0)	0 (0)	0 (0)	0 (0)	0 (0)	(0 0) (1 4) (0 (0)	0 (0)
	clear cell focus	0 (0)	0 (0) (0 (0 0)	0 (0)	0	0 (0) (0 0)	0 (0)	0 (0)	0 (0)	0 (0)		0 0) (6 25) (5 (21)	0 *

Grade 1 : Slight 2 : Moderate

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

b: Number of animals with lesion b

(c) c:b/a*100

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

3 : Marked

4 : Severe

(HPT150)

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

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

PAGE: 16

Organ	Findings	Group Name Control No. of Animals on Study 12 Grade 1 2 3 (%) (%) (%)	25ppm 5 5 4 (%) (%) (%) (%) (%)	100ppm 11 1 2 3 4 (%) (%) (%) (%)	400ppm 24 1 2 3 4 (%) (%) (%) (%)
{Digestive s	system)				
liver	acidophílic cell focus	<12> 0 0 0 0 0 0 0 0 0 0 0	<pre></pre>	<11> 0 0 0 0 0 0 0 0 0 0 0 0	3 3 0 0 (13) (13) (0) (0)
	basophilic cell focus	1 0 0 (8) (0) (0) (0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	1 0 0 0 (9) (9) (0) (0)	0 1 0 0 (0) (4) (0) (0)
	bile duct hyperplasia	1 1 0 (8) (8) (0) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	2 4 0 0 (18) (36) (0) (0)	3 6 0 0 (13) (25) (0) (0)
	biliary cyst	0 0 0 0 (0) (0 0 0 0 0 0	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (4) (0) (0)
Urinary sys	tem)				
idney	hyperplasia:tubular epithelial cell	0 0 0 (0) (0) (0) (0 0 0 0 0 0) (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	<24> 0 1 0 0 0 0 (4) (0) (0)
	deposit of hemosiderin	0 0 0 0 (0) (0) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (4) (0) (0)
	chronic nephropathy	2 1 0 (17) (8) (0) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	2 2 1 1 (18) (18) (9) (9)	6 13 1 0 ** (25) (54) (4) (0)

(HPT150)

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX

: FEMALE

DEAD AND MORIBUND ANIMALS (0-105W)

		Group Name No. of Animals on Study	12	ntrol	25ppm 5	100ppm 11	400ppm 24
drgan	Findings	Grade 1 (%)	(%)	3 4 (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%)
Urinary syst	cem}						
idney	tubular necrosis	0 (0)		0 0	(5) 0 0 0 0 (0) (0) (0) (0)	1 0 0 0 (9) (0) (0) (0)	<24> 0 0 0 0 0 0 0 0 0 0 0
	mineralization:papilla	0 (0)	0 (0 0	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (4) (0) (0)
	mineralization:pelvis	0 (0) (0 (0 0	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (4) (0) (0)
	glomerulosclerosis	0 (0) (0 0	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
Endocrine sy	stem}						
ituitary	angiectasis	0 (0) (0 0	<pre></pre>	0 0 0 0 (0) (0) (0) (0)	<24> 0 2 0 0 0 0 (8) (0) (0)
	cyst	0 (0) (0 0	0 0 0 0 0 (0) (0) (0)	0 1 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)
	hyperplasia	0 (0) (0 0	0 1 0 0 (0) (20) (0) (0)	0 0 0 0 0 (0) (0) (0)	1 0 0 0 (4) (0) (0) (0)

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

PAGE: 17

: RAT F344/DuCrj

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

PAGE: 18

Organ	Findings	Group Name	12 (%)	3 (%)	4 (%)	<u>1</u> (%)	2 (%)	5 3		<u>4</u> %)	1 (%)		11 2 %)	3 (%)	pm <u>4</u> (%)		<u>1</u> (%)	2 (%)	24	00ppn <u>3</u> %)	n <u>4</u> (%)
{Endocrine sy	rstem}																				
thyroid	C-cell hyperplasia	1 (8)	<123 0 (0) (0	0 0)	1 (20)	0	5> 0 (0)	((0)	0 (0)	(<111 0 0) (0	0 (0)	(0 0)	2	(24>	0 0) (0 0)
adrenal	hyperplasia:medulla	0 (0)	<123 0 (0) (0	0 0)	0 (0)	0	5> 0 (0)	())	0 (0)	(<11: 0 0) (> 0 0)	0 (0)	(1 4)	0	(24>	0 0) (0
{Reproductive	system}																				
uterus	blood retention	(8)	<12: 0 (0) (0	0 0)	0 (0)	0	5> 0 (0)	(())	0 (0)	(<111 0 0) (0	0 (0)	(0	0	(24>) ()	0
	cystic endometrial hyperplasia	0 (0)	1 (8) (0	0 0)	0 (0)	0 (0)	0 (0)	(())	0 (0)	(0 0) (0 0)	0 (0)	(2 8)	1 (4)	()) (0
vagina	blood retention	0 (0)	<12) 1 (8) (0	0 0)	0 (0)	0	5> 0 (0)	(()))	0 (0)		<11: 0 0) (0	0	(0 0)	0)) (0
{Nervous syst	em}																				
spinal cord	hemorrhage	0 (0)	<122 0 (0) (0	0 0)	(0)	0	5> 0 (0)	((1 (9)		<112 0 0) (0	0	(0 0)	0))) (0

(c)

c:b/a*100

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

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

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

Organ	Findings	Group Name Control No. of Animals on Study 12 Grade 1 2 3 4 (%) (%) (%) (%)	25ppm 5 1 2 3 4 (%) (%) (%) (%)	100ppm 11 12 3 4 (%) (%) (%) (%)	400ppm 24 1 2 3 4 (%) (%) (%) (%)
{Special sens	se organs/appendage)				
өуө	cataract	0 0 0 0 (0) (0) (0) (0		<11>> 0 0 0 0 0 0 0 0 0 0 0 0	(24) 1 0 0 0 (4) (0) (0) (0)
	retinal atrophy	0 0 0 0		0 0 0 0 0 (0) (0)	1 1 0 0 (4) (4) (0) (0)
	iritis	0 1 0 0		1 0 0 0 0 (9) (0) (0) (0)	0 0 0 0 0 (0)
	squamous cell metaplasia:cornea	0 0 0 0 0		0 0 0 0 0 (0) (0)	2 0 0 0 0 (8) (0) (0) (0)
{Musculoskele	etal system}				
bone	osteosclerosis	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		<11> 0 0 0 0 0 0 0 0 0 0 0 0	2 0 0 0 (8) (0) (0) (0)
{Body cavitie	es)				
peritoneum	inflammation	<12> 0 1 0 0 (0) (8) (0) (0		0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
Grade (a >	1: Slight 2: Moderate a: Number of animals examined at the b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: F				

APPENDIX L 6

HISTOPATHOLOGICAL FINDINGS:

NON-NEOPLASTIC LESIONS : SUMMARY,

RAT: FEMALE:

SACRIFICED ANIMALS

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : FEMALE PAGE: 13

Organ	:	Group Name Control No. of Animals on Study 38 Grade 1 2 3 (%) (%)	25ppm 45 4 (%) (%) (%) (%)	100ppm 39 1 2 3 4 (%) (%) (%) (%)	400ppm 26 1 2 3 4 (%) (%) (%) (%)
{Integumentar	y system/appandage}				
skin/app	inflammation	\(\lambda 38 \rangle \) \(0 2 0 \) \(0 \rangle (5 \rangle (0) (0 0 0 0 0 0) (0) (0) (0) (0)	<39> 0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<26> 0 1 0 0 (0) (4) (0) (0)
	epidermal cyst	0 0 0 (0) (0) (0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (0) (0)
(Respiratory	system}				
asal cavit	mineralization	38> 3 0 0 (8) (0) (0) (0 0 0 0 0 0) (0) (0) (0) (0)	39> 1 0 0 0 (3) (0) (0) (0)	<pre></pre>
	eosinophilic change:olfactory epitheli	1 25 11 (3) (66) (29) (0 0 25 20 0 0) (0) (56) (44) (0)	0 25 14 0 (0) (64) (36) (0)	0 23 2 0 (0) (88) (8) (0)
	eosinophilic change:respiratory epithe	0 0 0 (0) (0) (0 3 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	6 0 0 0 * (15) (0) (0) (0)	0 0 0 0 0 (0) (0)
	inflammation:foreign body	1 1 0 (3) (0) (0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	2 0 0 0 0 (5) (0) (0) (0)	1 1 0 0 (4) (4) (0) (0)
	inflammation:respiratory epithelium	0 0 0 0 (0) (0 3 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	4 0 0 0 0 (10) (10) (10)	6 0 0 0 ** (23) (0) (0) (0)

< a >

a : Number of animals examined at the site

b

b: Number of animals with lesion

(c)

c:b/a * 100

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

(HPT150)

BAIS4

: RAT F344/DuCrj

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

ANIMAL REPORT TYPE : A1

SEX : FEMALE

PAGE: 14

Organ	Findings	Group Name No. of Animals on Study Grade 1 (%)	38 2	Contro 3 (%)	1 <u>4</u> (%)	<u>1</u> (%)	2 (%)	25 45 3 (%)	4 (%)	<u> </u>	3 2 (%)	100p 9 3 (%)	pm 4 (%)	1 (%)	2 (%)	26 3)ppm 4 (%)	<u> </u>
{Respiratory	system)													-		,		
nasal cavit	respiratory metaplasia:olfactory e		<383 0 (0) (0	0 0)	1 (2)	0	45> 0 (0)	0 (0)	0 (0)	0	9> 0 (0)	0 (0)	0 (0)		26> 0 (0)	0 (0)	
	respiratory metaplasia:gland	10 (26)	15 (39) (0	0 0)	19 (42)	16 (36)	0 (0)	0 (0)	21 (54)	13 (33)	0 (0)	0 *	2 (8)	15 (58)	0 (0)	0 (0)	
	squamous cell metaplasia:respirato	ry epithelium 0 (0)	0 (0) (0	0 0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	7 (27)	4 (15)	0 (0)		**)
	hyperplasia with atypia:transition		0 (0) (0	0 0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	1 (4)	1 (4)	0 (0)	0 (0)	
	atrophy:olfactory epithelium	0 (0)	0 (0) (0	0	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	18 (69)	7 (27)	0 (0)		**)
	necrosis:olfactory epithelium	0 (0)	0 (0) (0	0 0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	5 (19)	0 (0)	0 (0)		*
lung	inflammatory infiltration	0 (0)	(0) (0	0 0)	0 (0)	0	15> 0 (0)	0 (0)	0 (0)	1	9> 0 (0)	0	0 (0)		26> 0 (0)	0 (0)	
	bronchiolar-alveolar cell hyperpla		0 (0) (0	0	0 (0)	·0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	

Grade 1 : Slight

2 : Moderate

3 : Marked

4 : Severe

< a > b

a: Number of animals examined at the site

b: Number of animals with lesion

c:b/a*100 (c)

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

ANIMAL : RAT F344/DuCrj

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

SACRIFICED ANIMALS (105W)

		roup Name o. of Animals on Study	Control 38	25ppm 45	100ppm 39	400ppm
Organ		rade 1	2 3 4 %) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	26 1 2 3 4 (%) (%) (%) (%)
{Hematopoieti	.c system)					
bone marrow	granulation		<38> 0 0 0 0) (0) (0)	<45> 4 1 0 0 (9) (2) (0) (0)	<39> 2 0 0 0 (5) (0) (0) (0)	<26> 1 1 0 0 (4) (4) (0) (0)
	histiocytosis		0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (4) (0) (0)
	increased hematopoiesis		0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	3 0 0 0 0 (7) (0) (0) (0)	1 0 0 0 0 (3) (0) (0) (0)	4 0 0 0 * (15) (0) (0) (0)
spleen	deposit of hemosiderin		<38> 2	<45> 1 40 0 0 (2) (89) (0) (0)	<39> 1 32 2 0 (3) (82) (5) (0)	<26> 0 17 0 0 * (0) (65) (0) (0)
	fibrosis:focal		0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)
	extramedullary hematopoiesis	0 (0) (1	4 0 0 1) (0) (0)	0 3 0 0 (0) (7) (0) (0)	0 3 1 0 (0) (8) (3) (0)	0 2 1 0 (0) (8) (4) (0)
{Circulatory	system)					
heart	inflammatory infiltration		<38> 0 0 0 0) (0) (0)	<45> 0 1 0 0 (0) (2) (0) (0)	<39> 0 0 0 0 0 0 0 0 0 0 0	<26> 0 0 0 0 0 0 0 0 0 0 0
Grade <a> b (c) Significant d	a: Number of animals examined at the siteb: Number of animals with lesionc: b / a * 100					

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : FEMALE

PAGE: 16

	Group Name No. of Animals on Study	Contro 38	L		25ppm 45		39	00ppm	4· 26	00ppm
Findings	Grade <u>1</u> (%)	2 3 (%) (%)	(%)	1 2 (%)	3 4 (%) (%)	(%)	2		1 2	3 <u>4</u> %) (%)
ystem)										
fibrosis:focal	0 (0)	<38> 0 0 (0) (0) (0 0) (1 1	0 0	0 (0) (
myocardial fibrosis	6 (16)	0 0	0 0) (10 0 22) (0)	0 0	11 (28) (2 5) (0 0 0 0) (0)		
tem}										
inflammation	0 (0)	<38> 0 0 (0) (0) (0 0) (0 0	0 0	0 (0) (
inflammation	0 (0)	<38> 0 0 (0) (0) (0 0) (0 0	0 0	0 (0) (
squamous cell hyperplasia	0 (0) (0 0 (0) (0 0) (0 0	0 0 (0)	0 (0) (2 5) (0 0 0) (0)		
arteritis	0 (0) (0 0 (0) (0 0) (0 0	0 0 (0)	1 (3) (0 (0)	0 0 0) (0)		
	fibrosis:focal myocardial fibrosis sem) inflammation inflammation	No. of Animals on Study Grade 1 (%) (%	No. of Animals on Study 38 Grade 1 2 3 (%) (%) (%) (%) (%) (%) (%) (%) (%) (%)	No. of Animals on Study 38 1 2 3 4 (%) (%) (%) (%) (%) (%) (%) (%) (%) (%)	No. of Animals on Study 38 1 2 3 4 (%) (%) (%) (%) (%) (%) (%) (%) (%) (%)	No. of Animals on Study 38	No. of Animals on Study 38 45 1 2 3 4 1 2 3 4 1 2 3 4 1 2 3 4 1 2 3 4 1 2 3 4 1 2 3 4 1 2 3 4 1 2 3 4 1 2 3 4 1 3	No. of Animals on Study 38	No. of Animals on Study 38	No. of Animals on Study 38 45 39 28 45 1 2 3 4 1 2 3 3 4 1 2 3 3 4 1 2 3 3 4 1 2 3 3 4 1 2 3 3 4 3 3 3 3 3 3 3

(HPT150)

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1 SEX : FEMALE

Organ	Findings	Group Name No. of Animals on Study Grade 1 (%)	Control 38 2 3 4 (%) (%) (%)	25ppm 45 1 2 3 4 (%) (%) (%) (%)	100ppm 39 1 2 3 4 (%) (%) (%) (%)	400ppm 26 1 2 3 4 (%) (%) (%) (%)
{Digestive :	system)					
stomach	basal cell hyperplasia	0 (0) (<38> 0 0 0 (0) (0) (0)	<45> 0 0 0 0 0 0 0 0 0 0 0 0	39> 1 0 0 0 (3) (0) (0) (0)	<26> 0 0 0 0 0 0 0 0 0 0 0 0
	hyperplasia:forestomach	(0) (1 0 0 (3) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
	erosion:glandular stomach	(0) (0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (3) (0) (0)	1 0 0 0 0 (4) (0) (0) (0)
	ulcor:glandular stomach	0 (0) (0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (4) (0) (0) (0)
	hyperplasia:glandular stomach	0 (0) (0 0 0 0 (0) (0)	0 1 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0)
	inflammation:glandular stomach	0 (0) (0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 1 0 0 (0) (0)
liver	herniation	(0) (<38> 7 0 0 (18) (0) (0)	<45> 0 8 0 0 (0) (18) (0) (0)	<39> 0 9 0 0 0 0 (23) (0) (0)	<26> 0 3 0 0 0 0) (12) (0) (0)
	necrosis:central	0 (0) (0 0 0 (0) (0)	0 1 0 0 (0) (2) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)

b b : Number of animals with lesion

c:b/a*100

(c)

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

(HPT150)

BAIS4

ANIMAL : RAT F344/DuCrj

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

SACRIFICED ANIMALS (105W)

PAGE: 18

Organ	Findings	Group Name No. of Animals on Study Grade(%)	38 2 (%)	Contro 3 (%)	1 (%)	<u>1</u> (%)	4: 2 (%)	25pj 5 3 (%)	om <u>4</u> (%)	<u>1</u> (%)	29	39 2	100pr 3 (%)	oin <u>4</u> (%)		1 (%)	2 (%)	400p 6 3 (%)	9pm 4 (%)
{Digestive	system)			, , , , , , , , , , , , , , , , , , , ,															
liver	granulation	7 (18)	<382 11 (29) (1	0 0)	5 (11)	<4! 5 (11)	0	0	0 (0)	1	<39> L 3) (0	0 ** (0)		1 4) (<22 2 8)	0	0 *
	inflammatory cell nest	0 (0)	2 (5) (0	0 0)	0 (0)	0 (0)	0	0 (0)	0 (0)			0	0 (0)		0 0) (0	0 (0)	0 (0)
	clear cell focus	3 (8)	1 (3) (0	0 0)	0 (0)	0	0	0 (0)	7 (18)	(())) (0 0)	0 (0)	(1 4) (6 23)	15 (58)	1 ** (4)
	acidophilic cell focus	0 (0)	0 (0) (0	0 0)	0 (0)	0	0	0 (0)	1 (3)	(())) (0	0 (0)	(1 4) (6 23)	0 (0)	0 ** (0)
	basophilic cell focus	14 (37)	8 (21) (0	0	8 (18)	5 (11)	0	0 * (0)	10 (26)	9 (23		0	0 (0)		1 4) (4 15)	0 (0)	0 ** (0)
	bile duct hyperplasia	0 (0)	2 (5) (0	0	4 (9)	7 (16)	0	0 * (0)	15 (38)	8 (21	3	0 0) (0 ** (0)		10 38) (3 12)	0 (0)	0 ** (0)
	biliary cyst	0 (0)	1 (3) (0	0	0 (0)	0	0	0	0 (0)	(())) (0 0) (0		0 0) (0	0 (0)	0 (0)
pancreas	atrophy	1 (3)	<38) 3 (8) (0	0 0)	1 (2)	<48 5 (11)	0	0 (0)	0 (0)	2		0 0) (0 (0)		0 0) (<28 2 8)	6> 0 (0)	0 (0)

Grade 1 : Slight 2 : Moderate

a : Number of animals examined at the site

3 : Marked

4 : Severe

b b: Number of animals with lesion

c:b/a*100

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

< a >

SEX

: RAT F344/DuCrj

: FEMALE

ANIMAL REPORT TYPE : A1 HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (105W)

PAGE: 19

		Group Name No. of Animals on Study	38	Contro	o1		4	25p)	pm			39	100p	om			26	400 ₁	ppm	
)rgan	Findings	Grade <u>1</u> (%)	(%)	3 (%)	(%)	(%)	2 (%)	3 (%)	(%)	<u>1</u> (%)	. <u></u>	2 (%)	3 (%)	(%)	<u>(</u>	<u>1</u> %)	2 (%)	(%)	(<u>4</u> (%)
Digestive s	ystem)																			
oancreas	hyperplasia	(0)	<38: 0 (0) (0	0 (0)	0 (0)	<4! 0 (0)	0	0 (0)	0 (0)	(<39 0 0) () 0 0)	0 (0)		0 0) (<26 1 4)	6> 0 (0)		0 0)
Urinary syst	tem}																			
cidney	hyperplasia:tubular epithelial cell	0 (0)	<38. 0 (0) (0	0	0 (0)	<45 0 (0)	0	0 (0)	0 (0)	(<39 1 3) (0 0 0)	0 (0)) ()	<26 1 4)	6> 0 (0)		0 0)
	deposit of hemosiderin	0 (0)	0 (0) (0	0 (0)	0 (0)	0	0 (0)	0 (0)	0 (0)	(0	0 0)	0 (0)) (1 4)	0 (0)		0 0)
	chronic nephropathy	18 (47)	1 (3) (0	0 (0)	11 (24)	12 (27)	1 (2)	0 ** (0)	17 (44)	(15 38) (0	0 ** (0)		3 :	18 69) (4 (15)		0 * 0)
	tubular necrosis	0 (0)	1 (3) (0	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	(0 (0	0))) (0	0		0 0)
	mineralization:papilla	0 (0)	2 (5) (0	0 (0)	0 (0)	4 9)	0 (0)	0	1 (3)	(0	0	0))) (0	0 (0)	((0 0)
	mineralization:pelvis	0 (0)	0 (0) (0	0 (0)	0 (0)	1 (2)	0	0 (0)	0 (0)	(2 5) (0	0))) (:	3 12) (0	(1	0 0)

Grade

1 : Slight

2 : Moderate

3 : Marked

4 : Severe

< a > b

a : Number of animals examined at the site

b: Number of animals with lesion

(c) c:b/a * 100

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

: RAT F344/DuCrj

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

ANIMAL REPORT TYPE : A1

SEX : FEMALE PAGE: 20

Organ	Findings	Group Name No. of Animals on Study Grade 1 (%)	38 	Contro 3 (%)	01 <u>4</u> (%)	1 (%)	2 (%)	25 45 3 (%)	9 ppm 4 (%)	1 (%)	2 (%)	100p 39 3 (%)	pm 4 (%)	<u>1</u> (%)	5)	26 2 (%)	400p 3 (%)	9pm 4 (%)
{Endocrine s	ystem)																	
pituitary	angiectasis	1 (3)	<382 4 (11) (0	0 (0)	3 (7)	4	45> 0 (0)	0 (0)	3 (8)	1	39> 0 (0)	0 (0)	0 (0)	ı)) (<26 1 4) (0	0 (0)
	cyst	2 (5)	2 (5) (0 0)	0 (0)	1 (2)	1 (2)	0 (0)	0 (0)	1 (3)	0	0 (0)	0 (0)	1 (4)		2 8) (0 (0)	0 (0)
	hyperplasia	2 (5)	7 (18) (0	0 (0)	3 (7)	11 (24)	0 (0)	0 (0)	4 (10)	5 (13)	0 (0)	0 (0)	3 (12)	;	4 15) (0 (0)	0 (0)
	Rathke pouch	0 (0)	0 (0) (0	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0))) (0	0 (0)	0 (0)
thyroid	cyst	0 (0)	<383 0 (0) (0	0 (0)	0 (0)	0	45> 0 (0)	0 (0)	0 (0)	0	39> 0 (0)	0 (0)	0 (0)		<26 1 4) (0	0 (0)
	ultimibranchial body remanet	0 (0)	1 (3) (0	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0	0 (0)	0 (0)	0 (0)		0 (0 (0)	0 (0)
	follicular hyperplasia	0 (0)	0 (0) (0	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)		1 4) (0	0 (0)
	C-cell hyperplasia	3 (8)	3 (8) (0	0 (0)	9 (20)	6 (13)	0 (0)	0 (0)	7 (18)	4 (10)	0 (0)	0 (0)	2 (8)		1 4) (0 (0)	0 (0)

Grade 1 : Slight 2 : Moderate

3 : Marked

4 : Severe

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

b : Number of animals with lesion

c:b/a*100

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

(HPT150)

b (c)

ANIMAL : RAT F344/DuCrj

: FEMALE

REPORT TYPE : A1 SEX

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (105W)

PAGE: 21

	И	roup Name fo. of Animals on Study Grade 1	Control 38	25ppm 45	100ppm 39	400ppm 26
Organ	Findings	(%)	2 3 4 (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)
{Endocrine sys	stem}					
adrena1	peliosis-like lesion	2 (5)	<38> 1 0 0 (3) (0) (0)	<45> 0 0 0 0 (0) (0) (0) (0)	<39> 0 1 0 0 (0) (3) (0) (0)	<26> 0 0 0 0 0 0 0 0 0) (0) (0) (0)
	hyperplasia:medulla	2 (5)	0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (3) (0) (0) (0)	0 0 0 0 0 (0) (0)
·	focal fatty change:cortex	0 (0)	1 0 0 (3) (0) (0)	2 3 0 0 (4) (7) (0) (0)	0 1 0 0 (0) (0) (0)	1 2 0 0 (4) (8) (0) (0)
{Reproductive	system)					
vary	cyst	0 (0)	<38> 0 0 0 (0) (0) (0)	<pre></pre>	<39> 0 1 0 0 (0) (3) (0) (0)	<26> 0 1 0 0 (0) (4) (0) (0)
terus	cystic endometrial hyperplasia	2 (5)	<38> 2 0 0 (5) (0) (0)	<45> 3 1 0 0 (7) (2) (0) (0)	<pre></pre>	<26> 4 0 0 0 (15) (0) (0) (0)
orep/cli gl	duct ectasia	0 (0)	<38> 1 0 0 (3) (0) (0)	<45> 0 1 0 0 (0) (2) (0) (0)	<39> 0 0 0 0 0 0 0 0 0 0 0	<26> 0 1 0 0 (0) (4) (0) (0)
(a) b (c)	1: Slight 2: Moderate 3: a: Number of animals examined at the sit b: Number of animals with lesion c: b / a * 100 ifference; *: P ≤ 0.05 **: P ≤					

(HPT150)

SEX

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

HISTOPATHOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (105W)

PAGE: 22

	No. of Animals on Study Grade 1 (%)	38 2 3 (%) (%)	(%)		45 2 3 %) (%)	<u>4</u> (%)	<u>1</u> (%)	39 2 (%)	(%)	<u>4</u> (%)	<u>1</u> (%)	2 (%)	26 3 (%)	(%)
;														
S														
	(0) (<38> 0 0 (0) (0)	0 (0) (1 2) (<45> 0 0 0) (0)	0 (0)	0 (0)	<39: 0 (0) (0	0 ()	0 (0)	0	26> 0 (0)	0 (0)
			0 (0) (1 2) (<45> 0 0 0) (0)	0 (0)	1 (3)	0	0	0 0)	0 (0)	0	0	0 (0)
appendage}														
rt	2 (5) (<38> 0 0 0) (0)	0 (0) (5 (11) (<45> 0 0 0) (0)	0 (0)	2 (5) (0	0	0 0)	0 (0)	0	0	0 (0)
atrophy	(0) (2 0 5) (0)	0 (0) (0 (1:	5 0 1) (0)	0 (0)	0 (0)	2 (5) (0	0	0 (0)	0 (0)	0 (0)	0 (0)
ation	0 (0) (<38> 0 0 0) (0)	0 (0) (0 (0)	1 (3) (0	0	0 0)	0 (0)	0	0	0 (0)
ation	2 (5) (<38> 5 0 13) (0)	0 (0) (0 (0)		1	0	0 0)	0 (0)	1	0	0
	appendage) ct I atrophy mation nt 2: Moderate 3: er of animals examined at the sit	appendage) ct 2 (5)(latrophy 0 (0)(nation 0 (0)(nation 2 (5)(tt 2: Moderate 3: Marked 4: Severe	0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 1 0 0 1 0 0 0 0 0 0 0 0 0 0 0	0	S	0 0 0 0 0 0 1 0 0 0 1 0 0 0 1 0 0 0 0 1 0	S	S	Seppendage) appendage) ct	appendage) st \[\begin{pmatrix} 0 & 0 & 0 & 0 & 1 & 0 & 0 & 0 & 1 & 0 & 0	appendage) ct	appendage) att 2: Moderate 3: Marked 4: Severe appendage 1

(HPT150)

BAIS4

ANIMAL : RAT F344/DuCrj

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)

REPORT TYPE : A1

SEX : FEMALE

SACRIFICED ANIMALS (105W)

		roup Name o. of Animals on S	tudv	38	Contro	ol			25 45	ppm		9	100 ₁ 39	opm			26	400pr	m
)rgan		rade	1 (%)	2 (%)	3 (%)	(%)	<u>(%)</u>	(%)	3 (%)		<u>1</u> (%)	2 (%)	3 (%)	(%)	(1 %)	2 (%)	3 (%)	<u>4</u> (%)
Musculoskele	tal system)																		
one	osteosclerosis		4 (11) (<383 0 0) (0	0	3 (7)	0	45> 0 (0)		3 (8)	3	39> 1 (3)	0 (0)	((0 0) (<260 0 0) (> 0 0) (0 (0)
rade a > b c) ignificant d	1: Slight 2: Moderate 3: a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 ifference; *: P ≤ 0.05 **: P ≤ 0	e	Severe																

APPENDIX M 1

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

RAT: MALE

(2-YEAR STUDY)

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

STUDY NO. : 0417

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1
SEX : MALE

ime-related Weeks	Items	Group Name	Control	25ppm	100ppm	400ppm
0 - 52	NO. OF EXAMINED ANIMALS		0	1	2	2
	NO. OF ANIMALS WITH TUMORS		0	1	1	1
	NO. OF ANIMALS WITH SINGLE TUMORS		Ö	1	1	1
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	0
	NO. OF BENIGN TUMORS		0	0	0	. 0
	NO. OF MALIGNANT TUMORS		0	1	1	1
	NO. OF TOTAL TUMORS		0	1	1	1
53 - 78	NO. OF EXAMINED ANIMALS		4	4	0	3
	NO. OF ANIMALS WITH TUMORS		3	4	0	1
	NO. OF ANIMALS WITH SINGLE TUMORS		2	4	0	1
	NO. OF ANIMALS WITH MULTIPLE TUMORS		1	0	ő	0
	NO. OF BENIGN TUMORS		1	2	0	1
	NO. OF MALIGNANT TUMORS		3	2	0	Õ
	NO. OF TOTAL TUMORS		4	4	0	1
79 - 104	NO. OF EXAMINED ANIMALS		6	10	10	15
	NO. OF ANIMALS WITH TUMORS		6	10	10	15
	NO. OF ANIMALS WITH SINGLE TUMORS		1	1	4	1
	NO. OF ANIMALS WITH MULTIPLE TUMORS		5	9	6	14
	NO. OF BENIGN TUMORS		9	19	9	27
	NO. OF MALIGNANT TUMORS		4	5	7	11
	NO. OF TOTAL TUMORS		13	24	16	38
105 - 105	NO. OF EXAMINED ANIMALS		40	35	38	30
	NO. OF ANIMALS WITH TUMORS		40	35	37	30
	NO. OF ANIMALS WITH SINGLE TUMORS		16	15	10	8
	NO. OF ANIMALS WITH MULTIPLE TUMORS		24	20	27	22
	NO. OF BENIGN TUMORS		73	53	67	64
	NO. OF MALIGNANT TUMORS		5	7	12	9
	NO. OF TOTAL TUMORS		78	60	79	73

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

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : MALE

Time-relatedWeeks	Items	Group Name	Control	25ppm	100ppm	400ppm	
0 - 105	NO. OF EXAMINED ANIMALS		50	50	50	50	
	NO. OF ANIMALS WITH TUMORS		49	50	48	47	
	NO. OF ANIMALS WITH SINGLE TUMORS		19	21	15	11	
	NO. OF ANIMALS WITH MULTIPLE TUMORS		30	29	33	36	
	NO. OF BENIGN TUMORS		83	74	76	92	
	NO. OF MALIGNANT TUMORS		12	15	20	21	
	NO. OF TOTAL TUMORS		95	89	96	113	

(HPT070)

BAIS4

APPENDIX M 2

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

RAT: FEMALE

(2-YEAR STUDY)

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

STUDY NO. : 0417

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

SEX : FEMALE

ime-related Weeks	Items	Group Name	Control	25ppm	100ppm	400ppm	
0 - 52	NO. OF EXAMINED ANIMALS		0	0	1	0	
	NO. OF ANIMALS WITH TUMORS		0	0	1	0	
	NO. OF ANIMALS WITH SINGLE TUMORS		n	0	1	0	
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	Ö	0	0	
	NO. OF BENIGN TUMORS		0	0	0	0	
	NO. OF MALIGNANT TUMORS		0	0	1	0	
	NO. OF TOTAL TUMORS		0	0	1	0	
53 - 78	NO. OF EXAMINED ANIMALS		3	1	1	3	
	NO. OF ANIMALS WITH TUMORS		1	0	1	3	
	NO. OF ANIMALS WITH SINGLE TUMORS		1	0	i	2	
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	1	
	NO. OF BENIGN TUMORS		1	0	0	2	
	NO. OF MALIGNANT TUMORS		0	0	1	3	
	NO. OF TOTAL TUMORS		1	0	1	5	
79 - 104	NO. OF EXAMINED ANIMALS		9	4	9 .	21	,
	NO. OF ANIMALS WITH TUMORS		7	3	8	21	
	NO. OF ANIMALS WITH SINGLE TUMORS		4	3	3	1	
	NO. OF ANIMALS WITH MULTIPLE TUMORS		3	0	5	20	
	NO. OF BENIGN TUMORS		7	2	11	27	
	NO. OF MALIGNANT TUMORS		3	1	3	31	
	NO. OF TOTAL TUMORS		10	3	14	58	
105 - 105	NO. OF EXAMINED ANIMALS		38	45	39	26 ·	
	NO. OF ANIMALS WITH TUMORS		25	30	26	25	
	NO. OF ANIMALS WITH SINGLE TUMORS		16	21	16	1	
	NO. OF ANIMALS WITH MULTIPLE TUMORS		9	9	10	24	
	NO. OF BENIGN TUMORS		29	37	34	46	
	NO. OF MALIGNANT TUMORS		6	3	3	28	
	NO. OF TOTAL TUMORS		35	40	37	74	

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS - TIME RELATED ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

SEX : FEMALE

PAGE: 4

Time-relatedWeeks	Items	Group Name	Control	25ppm	100ppm	400ppm	
0 - 105	NO. OF EXAMINED ANIMALS		50	50	50	50	
	NO. OF ANIMALS WITH TUMORS NO. OF ANIMALS WITH SINGLE TUMORS NO. OF ANIMALS WITH MULTIPLE TUMORS	•	33 21 12	33 24 9	36 21 15	49 4 45	
	NO. OF BENIGN TUMORS NO. OF MALIGNANT TUMORS NO. OF TOTAL TUMORS		37 9 46	39 4 43	45 8 53	75 62 137	

(HPT070)

BAIS4

APPENDIX N 1

HISTOPATHOLOGICAL FINDINGS:

NEOPLASTIC LESIONS: SUMMARY,

RAT: MALE

(2-YEAR STUDY)

: RAT F344/DuCrj

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

ANIMAL : RATREPORT TYPE : A1

SEX : MALE

Group Name Control 25ppm 100ppm 400ppm Organ_ Findings_ No. of animals on Study 50 50 50 50 {Integumentary system/appandage} skin/app <50> <50> <50> <50> squamous cell papilloma 1 (2%) 1 (2%) 1 (2%) 1 (2%) trichoepithelioma 0 (0%) 1 (2%) 0 (0%) 3 (6%) keratoacanthoma 1 (2%) 2 (4%) 0 (0%) 1 (2%) sebaceous adenoma 1 (2%) 0 (0%) 3 (6%) 0 (0%) squamous cell carcinoma 0 (0%) 0 (0%) 2 (4%) 0 (0%) subcutis <50> <50> <50> <50> fibroma 1 (2%) 7 (14%) 3 (6%) 1 (2%) leiomyoma 1 (2%) 1 (2%) 0 (0%) 0 (0%) osteoma 1 (2%) 0 (0%) 0 (0%) 0 (0%) hemangioma 0 (0%) 0 (0%) 0 (0%) 1 (2%) brown fat <50> <50> <50> <50> liposarcoma 0 (0%) 1 (2%) 0 (0%) 0 (0%) {Respiratory system} nasal cavit <50> <50> <50> <50> ethesioneuroepithelioma 0 (0%) 0 (0%) 0 (0%) 1 (2%) lung <50> ⟨50⟩ <50> <50> bronchiolar-alveolar adenoma 2 (4%) 1 (2%) 1 (2%) 7 (14%) (a) a: Number of animals examined at the site b (c) b: Number of animals with neoplasm c:b/a*100

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : MALE

Organ		Group Name No. of animals on Study	Control 50	25ppm 50	100ppm 50	400ppm 50
{Respiratory	system)					
lung	bronchiolar—alveolar carcinoma	(<50> 0 (0%)	<50> 2 (4%)	<50> 0 (0%)	<50> 0 (0%)
{Hematopoieti	c system)					
lymph node	malignant lymphoma		<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)
thymus	thymoma:benign	:	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)
spleen	hemangioma	(<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)
	leiomyosarcoma	:	1 (2%)	0 (0%)	0 (0%)	0 (0%)
	histiocytic sarcoma	(0 (0%)	1 (2%)	0 (0%)	0 (0%)
	mononuclear cell leukemia	;	3 (6%)	3 (6%)	4 (8%)	4 (8%)
{Circulatory :	system)					
heart	atriocaval node tumor:benign	ſ	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)
{Digestive sys	stem}					
oral cavity	squamous cell papilloma	(<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)	<50> 1 (2%)
	squamous cell carcinoma	(0%)	0 (0%)	0 (0%)	1 (2%)
(a) b (c)	a: Number of animals examined at the site b: Number of animals with neoplasm c:b/a*10	0				
(HPT085)						

: RAT F344/DuCrj

HISTOPATHOLOGICAL FINDINGS: NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1 SEX : MALE

ANIMAL

Group Name Control 25ppm100ppm 400ppm Findings_ Organ_ No. of animals on Study 50 50 50 (Digestive system) small intes <50> <50> <50> <50> leiomyosarcoma 0 (0%) 0 (0%) 2 (4%) 1 (2%) large intes <50> <50> <50> <50> adenoma 0 (0%) 0 (0%) 0 (0%) 3 (6%) adenocarcinoma 0 (0%) 0 (0%) 0 (0%) 1 (2%) liver <50> <50> ⟨50⟩ <50> hepatocellular adenoma 1 (2%) 1 (2%) 2 (4%) 10 (20%) hemangiosarcoma 1 (2%) 0 (0%) 0 (0%) 2 (4%) hepatocellular carcinoma 0 (0%) 0 (0%) 1 (2%) 6 (12%) pancreas <50> <50> <50> <50> islet cell adenoma 3 (6%) 3 (6%) 2 (4%) 0 (0%) acinar cell adenoma 0 (0%) 0 (0%) 0 (0%) 1 (2%) ductal adenocarcinoma 0 (0%) 0 (0%) 0 (0%) 1 (2%) {Urinary system} kidney <50> <50> <50> <50> renal cell adenoma 0 (0%) 0 (0%) 0 (0%) 1 (2%) urin bladd <50> <50> <50> <50> transitional cell papilloma 0 (0%) 0 (0%) 2 (4%) 1 (2%) {Endocrine system} pituitary <50> <50> <50> <50> adenoma 8 (16%) 6 (12%) 7 (14%) 4 (8%) < a > a: Number of animals examined at the site

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

0. . 0417

: RAT F344/DuCrj

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1 SEX : MALE

ANIMAL

Group Name Control 25ppm 100ppm 400ppm Organ__ Findings_ No. of animals on Study 50 50 50 50 (Endocrine system) pituitary <50> <50> <50> <50> adenocarcinoma 1 (2%) 0 (0%) 0 (0%) 0 (0%) thyroid <50> ⟨50⟩ <50> <50> C-cell adenoma 8 (16%) 4 (8%) 4 (8%) 3 (6%) follicular adenoma 1 (2%) 1 (2%) 2 (4%) 2 (4%) C-cell carcinoma 0 (0%) 3 (6%) 0 (0%) 1 (2%) follicular adenocarcinoma 1 (2%) 0 (0%) 1 (2%) 0 (0%) parathyroid <50> <50> <50> <50> adenoma 0 (0%) 0 (0%) 0 (0%) 1 (2%) adrenal <50> <50> <50> <50> pheochromocytoma 3 (6%) 3 (6%) 3 (6%) 2 (4%) cortical adenoma 0 (0%) 0 (0%) 0 (0%) 1 (2%) pheochromocytoma:malignant 3 (6%) 1 (2%) 0 (0%) 0 (0%) {Reproductive system} testis <50> <50> <50> <50> interstitial cell tumor 45 (90%) 39 (78%) 39 (78%) 42 (84%) epididymis <50> <50> <50> <50> histiocytic sarcoma 0 (0%) 0 (0%) 0 (0%) 1 (2%) prostate <50> <50> <50> <50> adenoma 1 (2%) 0 (0%) 0 (0%) 1 (2%)

< a >

a: Number of animals examined at the site

b (c) b: Number of animals with neoplasm

c:b/a * 100

SEX

: MALE

: RAT F344/DuCrj

HISTOPATHOLOGICAL FINDINGS: NEOPLASTIC LESIONS (SUMMARY)

ANIMAL REPORT TYPE : A1

ALL ANIMALS (0-105W)

Group Name Control 25ppm 100ppm 400ppm Organ_ Findings_ No. of animals on Study 50 50 50 50 (Reproductive system) mammary gl <50> <50> <50> <50> adenoma 2 (4%) 0 (0%) 0 (0%) 0 (0%) fibroma 0 (0%) 1 (2%) 0 (0%) 0 (0%) fibroadenoma 0 (0%) 1 (2%) 0 (0%) 0 (0%) prep/cli gl <50> <50> <50> <50> adenoma 2 (4%) 1 (2%) 2 (4%) 4 (8%) {Nervous system} brain <50> ⟨50⟩ <50> <50> meningioma:benign 0 (0%) 1 (2%) 0 (0%) 0 (0%) glioma 0 (0%) 0 (0%) 1 (2%) 0 (0%) {Special sense organs/appendage} Zymbal gl <50> <50> <50> <50> Zmbal gland tumor:benign 0 (0%) 0 (0%) 1 (2%) 0 (0%) squamous cell carcinoma 0 (0%) (0%) 0 (0%) 1 (2%) Zymbal gland tumor:malignant 0 (0%) 1 (2%) 1 (2%) 0 (0%) {Musculoskeletal system} bone ⟨50⟩ <50> ⟨50⟩ <50> osteoma 0 (0%) 0 (0%) 1 (2%) 0 (0%) (a) a : Number of animals examined at the site b (c) b: Number of animals with neoplasm c:b/a * 100

⁽HPT085)

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

HISTOPATHOLOGICAL FINDINGS: NEOPLASTIC LESIONS (SUMMARY)

REPORT TYPE : A1

: MALE SEX

Group Name Control 25ppm 100ppm 400ppm Organ_ Findings_ No. of animals on Study 50 50 50 50 (Musculoskeletal system) bone <50> <50> <50> <50> osteosarcoma 1 (2%) 1 (2%) 1 (2%) 0 (0%) (Body cavities) peritoneum <50> <50> <50> <50> mesothelioma 0 (0%) 2 (4%) 7 (14%) 1 (2%) retroperit <50> <50> <50> <50> neuroendocrine cell tumor:benign 0 (0%) 0 (0%) 1 (2%) 0 (0%) (a) a: Number of animals examined at the site b (c) b: Number of animals with neoplasm c:b/a * 100 (HPT085) BAIS4

APPENDIX N 2

HISTOPATHOLOGICAL FINDINGS:

NEOPLASTIC LESIONS: SUMMARY,

RAT: FEMALE

(2-YEAR STUDY)

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : FEMALE

brgan	Findings	Group Name No. of animals on Study	Control 50	25ppm 50	100ppm 50	400ppm 50
Integumenta	ry system/appandage)					
kin/app	squamous cell papilloma		<50>	<50>	<50>	<50>
			1 (2%)	0 (0%)	0 (0%)	1 (2%)
	trichoepithelioma	'	0 (0%)	0 (0%)	1 (2%)	2 (4%)
	basal cell epithelioma		0 (0%)	0 (0%)	1 (2%)	0 (0%)
bcutis	fibroma	ı	<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)
	osteosarcoma		0 (0%)	0 (0%)	1 (2%)	0 (0%)
espiratory	system}			,	\ _,,,	
sal cavit			<50>	<50>	<50>	< 50>
	adenoma		0 (0%)	0 (0%)	1 (2%)	0 (0%)
	chondroma	ı	0 (0%)	0 (0%)	1 (2%)	0 (0%)
ng	bronchiolar—alveolar adenoma		<50> 1 (2%)	<50> 0 (0%)	<50> 1 (2%)	<50> 5 (10%)
ematopoieti	ic system)					
mph node	malignant lymphoma		<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)
leen	hemangioma		<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)	<50> 2 (4%)
	mononuclear cell leukemia	!	5 (10%)	3 (6%)	5 (10%)	13 (26%)
< a >	a : Number of animals examined at the site					

: 0417

: RAT F344/DuCrj

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

REPORT TYPE : A1 SEX : FEMALE

ANIMAL

Group Name Control 25ppm 100ppm 400ppm Organ_ Findings_ No. of animals on Study 50 50 50 50 (Digestive system) oral cavity <50> <50> <50> <50> squamous cell papilloma 0 (0%) 0 (0%) 0 (0%) 1 (2%) tongue <50> <50> ⟨50⟩ <50> squamous cell papilloma 0 (0%) 0 (0%) 0 (0%) 1 (2%) stomach <50> <50> <50> <50> leiomyosarcoma 0 (0%) 0 (0%) 0 (0%) 1 (2%) large intes <50> <50> <50> <50> adenoma 0 (0%) 0 (0%) 0 (0%) 2 (4%) liver <50> <50> <50> <50> hemangioma 0 (0%) 0 (0%) 0 (0%) 1 (2%) hepatocellular adenoma 1 (2%) 0 (0%) 2 (4%) 32 (64%) hemangiosarcoma 0 (0%) 0 (0%) 0 (0%) 6 (12%) hepatocellular carcinoma 0 (0%) 0 (0%) 0 (0%) 38 (76%) pancreas <50> <50> <50> <50> islet cell adenoma 0 (0%) 1 (2%) 0 (0%) 0 (0%) {Urinary system} urin bladd <50> <50> <50> <50> transitional cell papilloma 0 (0%) 1 (2%) 1 (2%) 0 (0%) {Endocrine system} pituitary <50> ⟨50⟩ <50> <50> adenoma 9 (18%) 9 (18%) 9 (18%) 6 (12%) <a>> a: Number of animals examined at the site b (c) b: Number of animals with neoplasm c:b/a * 100

⁽HPT085)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)

ALL ANIMALS (0-105W)

SEX : FEMALE

Organ	Findings	Group Name No. of animals on Study	Control 50	25ppm 50	100ppm 50	400ppm 50
(Endocrine sy	stem)					
pituitary	adenocarcinoma		<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)
hyroid	C-cell adenoma		<50> 6 (12%)	<50> 7 (14%)	<50> 7 (14%)	<50> 5 (10%)
	follicular adenoma		2 (4%)	0 (0%)	0 (0%)	1 (2%)
	C-cell carcinoma		1 (2%)	1 (2%)	1 (2%)	0 (0%)
	follicular adenocarcinoma		0 (0%)	0 (0%)	0 (0%)	1 (2%)
drenal	pheochromocytoma		<50> 2 (4%)	<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)
Reproductive	system)					
ary/	granulosa-theca cell tumor		<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)	<50> 1 (2%)
terus	hemangioma		<50> 0 (0%)	<50> 1 (2%)	<50> 0 (0%)	<50> 1 (2%)
	endometrial stromal polyp		7 (14%)	6 (12%)	7 (14%)	7 (14%)
	yolk sack tumor:malignant		1 (2%)	0 (0%)	0 (0%)	0 (0%)
ammary gl	fibroadenoma		<50> 6 (12%)	<50> 9 (18%)	<50> 10 (20%)	<50> 3 (6%)
rep/cli gl	adenoma		<50> 1 (2%)	<50> 3 (6%)	<50> 4 (8%)	<50> 3 (6%)
<a>> (c)	a: Number of animals examined at the site b: Number of animals with neoplasm c:b/a	* 100				

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : FEMALE

Organ	Findings No. of animals o	Control on Study 50	25ppm 50	100ppm 50	400ppm 50
{Nervous syst	tem)				
rain	glioma	<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)	<50> 1 (2%)
Special sens	se organs/appendage)				
Zymbal gl	squamous cell carcinoma	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)
Musculoskele	etal system)				
one	osteosarcoma	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)	<50> 1 (2%)
Body cavitie	es)				
dipose	lipoma	<50> 1 (2%)	<50> 0 (0%)	<50> 0 (0%)	<50> 0 (0%)
<a>>	a: Number of animals examined at the site b: Number of animals with neoplasm c: b/a * 100		·		
HPT085)					

APPENDIX O 1

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS,

RAT: MALE

(2-YEAR STUDY)

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANIMAL : RAT F344/DuCrj SEX : MALE PAGE: 1

Group Name	Control	25ppm	100ppm	400ppm
	SITE : skin/appendage			
Tumor rate	TUMOR : trichoepithelioma			
Overall rates(a)	0/50(0.0)	1/50(2.0)	0/50(0.0)	0/50/ 0.0)
Adjusted rates(b)	0. 0	2. 86	0.0	3/50(6.0) 6.67
Terminal rates(c)	0/40(0.0)	1/35(2.9)	0/38(0.0)	2/30(6.7)
Statistical analysis		-, ,	0,000	2/30(3.1)
Peto test				
Standard method(d)	P = 0.1436			
Prevalence method(d)	P = 0.0567			
Combined analysis(d)	P = 0.0145*			
Cochran-Armitage test(e) Fisher Exact test(e)	P = 0.0266*	P = 0.5000	D. N.G.	D 0.4640
Tioner Dadet test(e)		P 0. 5000	P = N. C.	P = 0.1212
	SITE : skin/appendage			
	TUMOR : sebaceous adenoma			
Tumor rate	Tomon - Sobdoods additional			
Overall rates(a)	1/50(2.0)	0/50(0.0)	3/50(6.0)	0/50(0.0)
Adjusted rates(b)	2, 50	0.0	7. 89	0.0
Terminal rates(c)	1/40 (2.5)	0/35(0.0)	3/38(7.9)	0/30(0.0)
Statistical analysis				
Peto test				
Standard method(d) Prevalence method(d)	P = P = 0.6672			
Combined analysis(d)	P = 0.0072 P =			
Cochran-Armitage test(e)	P = 0.4761			
Fisher Exact test(e)	1 0. 1:01	P = 0.5000	P = 0.3087	P = 0.5000
		1 0.0000	1 - 0.3001	r - 0, 5000
	SITE : skin/appendage			
		keratoacanthoma, squamous cell carci	noma	
Tumor rate				
Overall rates(a)	2/50(4.0)	3/50(6.0)	3/50(6.0)	2/50(4.0)
Adjusted rates(b)	5. 00	8. 57	5. 26	5. 41
Terminal rates(c)	2/40(5.0)	3/35(8.6)	2/38(5, 3)	1/30(3.3)
Statistical analysis Peto test				
Standard method(d)	P = 0.3420			
Prevalence method(d)	P = 0.5403			
Combined analysis(d)	P = 0.5630			
Cochran-Armitage test(e)	P = 0.7797			
Fisher Exact test(e)	•••••	P = 0.5000	P = 0.5000	P = 0.6913

(HPT360A)

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

STUDY No. : 0417

ANIMAL : RAT F344/DuCrj SEX : MALE

Struct Name Control 25ppa 100ppan 400ppan 400ppan						
TUMOR : fibroms TUMOR : fibroms TUMOR Tibroms Tumor Tu	Group Name	Control	25ppm	100ppm	400ppm	
Name Tate Name		SITE : subcutis				
Overall rates (a) 1/50 (2.0) 7/50 (14.0) 3/50 (5.0) 1/50 (2.0) 3/50 (5.0) 3/50 (_	TUMOR : fibroma				
Adjusted rates (b)						
Terminal rates (c)						
Statistical analysis Peto test Standard method(d)						
Peto test Standard method (d)		1/40(2.5)	3/35(8.6)	3/38(7.9)	1/30(3.3)	
Standard method(d)	•					
Prevalence method(d)		P = 0.8065				
Combined analysis(d)						
P = 0.1912						
Fisher Exact test(e) P = 0.0297* P = 0.3087 P = 0.7525 SITE : lung TUMOR : bronchiolar-alveolar adenoms Fumor rate Overall rates(a) Adjusted rates(b) 5.00 2/50 (4.0) 1/50 (2.0) 1/50 (2.0) 1/50 (2.0) 7/50 (14.0) 2.56 2.63 20.00 Forminal rates(c) 2/40 (5.0) 0/35 (0.0) 1/38 (2.6) 5.00 2/40 (5.0) 2/40 (5.0) 2/40 (5.0) 1/38 (2.6) 5.00 P = Prevelence method(d) P = Cocbined analysis(d) P = 0.0023** Cocbined analysis(d) P = 0.0040** Fisher Exact test(e) P = 0.0020** Overall rates(a) 4/50 (4.0) 3/50 (6.0) 7/50 (1.0) 3/50 (5.0) 7/50 (1.0) 4/3014 (7.50) 1/38 (2.6) 5.00 7/50 (14.0) 4/3014 (7.50) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 5.00 7/50 (1.0) 5.00 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 5.00 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 5.00 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 5.00 7/50 (1.0) 5.00 5.00 7/50 (1.0) 5.00 5.00 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 7/50 (1.0) 5.00 5.00 5.00 5.00 7/50 (1.0) 5.00 5.00 7/50 (1.0) 5.00 5.0						
SITE : lung TUMOR : bronchiolar—alveolar adenoms			P = 0.0297*	P = 0.3087	P = 0.7525	
TUMOR : bronchiolar—alveolar adenoms TUMOR Tumor rate Tumor ra						
TUMOR : bronchiolar—alveolar adenoms		SITE : Lung				
Tumor rate Overall rates(a)		<u> </u>	adonoma			
Overall rates(a) 2/50(4.0) 1/50(2.0) 1/50(2.0) 7/50(14.0) Adjusted rates(b) 5.00 2.56 2.63 20.00 Terminal rates(c) 2/40(5.0) 0/35(0.0) 1/38(2.6) 6/30(20.0) Statistical analysis Peto test Standard method(d) P = Prevalence method(d) P = P = 0.0023** Combined analysis(d) P = P = 0.0040** Fisher Exact test(e) P = 0.0040** P = 0.5000 P = 0.5000 P = 0.0798 Tumor rate Overall rates(a) 2/50(4.0) 3/50(6.0) 1/50(2.0) 7/50(14.0) Adjusted rates(b) 5.00 7.69 2.63 20.00 Terminal rates(c) 2/40(5.0) 2/35(5.7) 1/38(2.6) 6/30(20.0) Statistical analysis P = P = P = Peto test Standard method(d) P = P = Combined method(d) P = 0.0108*	Tumor rate	Tomon . Dionomotal alveolal	adenona			
Adjusted rates (b) 5.00 2.56 2.56 2.63 20.00 Terminal rates (c) 2/40 (5.0) 0/35 (0.0) 1/38 (2.6) 6/30 (20.0) Statistical analysis Peto test Standard method (d) P =		2/50(4.0)	1/50(2.0)	1/50(2.0)	7/50(1/ 0)	
Terminal rates(c) 2/40(5.0) 0/35(0.0) 1/38(2.5) 6/30(20.0) Statistical analysis Peto test Standard method(d) P =	Adjusted rates(b)					
Standard method(d) P = Prevalence method(d) P = 0.0023** Combined analysis(d) P = Cochran-famitage test(e) P = 0.0040** Fisher Exact test(e) P = 0.5000 P = 0.5000 P = 0.0798 SITE : lung TUMOR : bronchiolar-alveolar adenoma, bronchiolar-alveolar carcinoma Numor rate Overall rates(a) 2/50(4.0) 3/50(6.0) 1/50(2.0) 7/50(14.0) Adjusted rates(b) 5.00 7.69 2.63 20.00 Terminal rates(c) 2/40(5.0) 2/35(5.7) 1/38(2.6) 6/30(20.0) Statistical analysis Peto test Standard method(d) P = Prevalence method(d) P = 0.0108* Combined analysis(d) P =	Terminal rates(c)	2/40(5.0)				
Standard method(d)	Statistical analysis				5, 55 (25, 5,	
Prevalence method(d)						
Combined analysis(d) P =		-				
Cochran-Armitage test(e)						
Fisher Exact test(e) P = 0.5000 P = 0.5000 P = 0.0798 SITE : lung TUMOR : bronchiolar—alveolar adenoma, bronchiolar—alveolar carcinoma Tumor rate Overall rates(a) Adjusted rates(b) 5.00 7.69 2.63 20.00 Terminal rates(c) Statistical analysis Peto test Standard method(d) P = Prevalence method(d) Combined analysis(d) P = Prevalence method(d) P = 0.0108* Combined analysis(d) P = Prevalence method(d) P = 0.0108*	-	_				
SITE : lung TUMOR : bronchiclar—alveolar adenoma, bronchiclar—alveolar carcinoma Tumor rate Overall rates(a)		P = 0.0040**				
TUMOR: bronchiolar—alveolar adenoma, bronchiolar—alveolar carcinoma Tumor rate Overall rates(a)	risher Exact test(e)		P = 0.5000	P = 0.5000	P = 0.0798	
TUMOR: bronchiolar—alveolar adenoma, bronchiolar—alveolar carcinoma Tumor rate Overall rates(a)		SITE : lung				
Tumor rate Overall rates(a) 2/50 (4.0) 3/50 (6.0) 1/50 (2.0) 7/50 (14.0) Adjusted rates(b) 5.00 7.69 2.63 20.00 Terminal rates(c) 2/40 (5.0) 2/35 (5.7) 1/38 (2.6) 6/30 (20.0) Statistical analysis Peto test Standard method(d) P = Prevalence method(d) P = 0.0108* Combined analysis(d) P =			adenoma, bronchiolar—alveolar carcinoma			
Adjusted rates(b) 5.00 7.69 2.63 20.00 Terminal rates(c) 2/40(5.0) 2/35(5.7) 1/38(2.6) 6/30(20.0) Statistical analysis Peto test Standard method(d) P = Prevalence method(d) P = 0.0108* Combined analysis(d) P =						
Adjusted rates(b) 5.00 7.69 2.63 20.00 Terminal rates(c) 2/40(5.0) 2/35(5.7) 1/38(2.6) 6/30(20.0) Statistical analysis Peto test Standard method(d) P = Prevalence method(d) P = 0.0108* Combined analysis(d) P =		2/50(4.0)	3/50(6.0)	1/50(2.0)	7/50 (14. 0)	
Statistical analysis Peto test Standard method(d)				2. 63	The state of the s	
Peto test Standard method(d)		2/40(5.0)	2/35(5,7)	1/38(2.6)	6/30(20.0)	
Standard method(d) P = Prevalence method(d) P = 0.0108* Combined analysis(d) P =	•					
Prevalence method(d) $P = 0.0108*$ Combined analysis(d) $P =$						
Combined analysis(d) P =		-				
voolitain millitage cost(e) I = 0.0220↑	•	-				
Fisher Exact test(e) $P = 0.5000$ $P = 0.5000$ $P = 0.0798$		1 - 0.02254	P = 0.5000	D = 0 E000	D 0.0500	

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

STUDY No. : 0417

ANIMAL : RAT F344/DuCrj SEX : MALE

Course Name	0 - +- 1	0.5			
Group Name	Control	25ppm	100ppm	400ppm	
	SITE : spleen				
_	TUMOR : mononuclear cell leukemia				
Tumor rate					
Overall rates(a)	3/50 (6.0)	3/50(6.0)	4/50(8.0)	4/50(8.0)	
Adjusted rates(b)	5. 00	2. 86	5. 26	10.00	
Terminal rates(c)	2/40(5.0)	1/35(2.9)	2/38(5.3)	3/30(10.0)	
tatistical analysis					
Peto test					
Standard method(d)	P = 0.5829				
Prevalence method(d)	P = 0.1273				
Combined analysis(d)	P = 0.2474				
Cochran-Armitage test(e)	P = 0.6798				
Fisher Exact test(e)		P = 0.6611	P = 0.5000	P = 0.5000	
	SITE : large intestine				
	TUMOR : adenoma				
umor rate	TOMOR . adenoma				
Overall rates(a)	0/50(0.0)	0/50(0.0)	0/50(0.0)	2/50/ 6.0	
Adjusted rates(b)	0.0	0.0	0,00	3/50(6.0)	
Terminal rates(c)	0/40(0.0)	0/35(0.0)	0/38(0.0)	10.00	
Statistical analysis	0, 10 (0.0)	0/33(0.0/	0/38(0.0)	3/30(10.0)	
Peto test					
Standard method(d)	P =				
Prevalence method(d)	P = 0.0008**?				
Combined analysis(d)	P =				
Cochran-Armitage test(e)	P = 0.0033**				
Fisher Exact test(e)		P = N. C.	P = N. C.	P = 0.1212	
		1 14.0.	r - N. C.	r = 0.1212	
	SITE : large intestine				
	TUMOR : adenoma, adenocarcinoma				
Cumor rate	. /				
Overall rates(a)	0/50(0.0)	0/50(0.0)	0/50(0.0)	4/50(8.0)	
Adjusted rates(b)	0.0	0.0	0.0	10.00	
Terminal rates(c)	0/40(0.0)	0/35(0.0)	0/38(0.0)	3/30(10.0)	
Statistical analysis					
Peto test	D 0.4540				
Standard method(d)	P = 0.1512				
Prevalence method(d)	P = 0.0008**?				
Combined analysis(d)	P = 0.0001**?				
Cochran-Armitage test(e)	P = 0.0007**				
Fisher Exact test(e)		P = N. C.	P = N. C.	P = 0.0587	

(HPT360A)

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

STUDY No. : 0417

ANIMAL : RAT F344/DuCrj

SEX : MALE

Group Name	Control	25ppm	100ppm	400ppm	
	SITE : liver				
fumor rate	TUMOR : hepatocellular aden	oma			
Overall rates(a)	1/50(2.0)	1/50(2.0)	2/50(4.0)	10/50/ 20 0)	
Adjusted rates(b)	2. 50	2. 86	5. 26	10/50 (20. 0) 25. 81	
Terminal rates(c)	1/40(2.5)	1/35(2.9)	2/38(5.3)	7/30(23.3)	
Statistical analysis			_, ,	1,000	
Peto test					
Standard method(d)	P =				
Prevalence method(d)	P < 0.0001**				
Combined analysis(d) Cochran-Armitage test(e)	P = P < 0.0001**				
Fisher Exact test(e)	1 (0.000174	P = 0.7525	P = 0.5000	P = 0.0039**	
		1 0.1020	1 0.0000	1 - 0.0039##	
	SITE : liver				
	TUMOR : hepatocellular carc	inoma			
Tumor rate					
Overall rates(a)	0/50(0.0)	0/50(0.0)	1/50(2.0)	6/50(12.0)	
Adjusted rates(b)	0.0	0.0	2. 63	10.81	
Terminal rates(c)	0/40(0.0)	0/35(0.0)	1/38(2.6)	3/30(10.0)	
Statistical analysis Peto test					
Standard method(d)	P = 0.0145* ?				
Prevalence method(d)	P = 0.0023**				
Combined analysis(d)	P = 0.0001**				
Cochran-Armitage test(e)	P = 0.0001**				
Fisher Exact test(e)		P = N.C.	P = 0.5000	P = 0.0133*	
	SITE : liver				
•	TUMOR : hepatocellular aden	oma, hepatocellular carcinoma			
Constant	1/50/ 0.0)	4 (70 (. 0. 1)			
Overall rates(a) Adjusted rates(b)	1/50(2.0)	1/50(2.0)	3/50(6.0)	15/50(30.0)	
Terminal rates(c)	2. 50 1/40 (2. 5)	2. 86	7. 89	35. 48	
Statistical analysis	1/ 30(2.0/	1/35(2.9)	3/38(7.9)	10/30(33.3)	
Peto test					
Standard method(d)	P = 0.0145*?				
Prevalence method(d)	P < 0.0001**				
Combined analysis(d)	P < 0.0001**				
Cochran-Armitage test(e)	P < 0.0001**				
Fisher Exact test(e)		P = 0.7525	P = 0.3087	P = 0,0001**	

(HPT360A)

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

STUDY No. : 0417 ANIMAL : RAT F344/DuCrj

SEX : MALE

PAGE: 5

Group Name	Control	25ppm	100ppm	400ppm
	SITE : pancreas			
There is a second of the secon	TUMOR : islet cell adenoma			
Tumor rate Overall rates(a)	3/50(6.0)	2/50/ 6 0)	0/50/ 4.0)	0/50(0.0)
Adjusted rates(b)	6. 98	3/50 (6. 0) 6. 67	2/50 (4. 0) 5. 26	0/50(0.0)
Terminal rates(c)	2/40(5.0)	2/35(5.7)	2/38(5.3)	0.0 0/30(0.0)
Statistical analysis	2, 10 (0.0)	2/00(0.1)	2/30(3.3/	0/30(0.0)
Peto test				
Standard method(d)	P =			
Prevalence method(d)	P = 0.9739			
Combined analysis(d)	P =			
Cochran-Armitage test(e)	P = 0.0795			
Fisher Exact test(e)		P = 0.6611	P = 0.5000	P = 0.1212
	CTER			
	SITE : pituitary gland TUMOR : adenoma			
Tumor rate				
Overall rates(a)	8/50 (16.0)	6/50(12.0)	7/50(14.0)	4/50(8,0)
Adjusted rates(b)	13.64	5. 71	11. 63	8. 57
Terminal rates(c)	5/40 (12.5)	2/35(5.7)	3/38(7.9)	1/30(3.3)
Statistical analysis				,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Peto test				
Standard method(d)	P = 0.8284			
Prevalence method(d)	P = 0.7038			
Combined analysis(d)	P = 0.8512			
Cochran-Armitage test(e) Fisher Exact test(e)	P = 0.2651	D 0.0051		
Pisher Exact test(e)		P = 0.3871	P = 0.5000	P = 0.1783
	SITE : pituitary gland			
	TUMOR : adenoma, adenocarcinoma			
Tumor rate	,			
Overall rates(a)	9/50(18.0)	6/50(12.0)	7/50(14.0)	4/50(8.0)
Adjusted rates(b)	13. 64	5. 71	11. 63	8. 57
Terminal rates(c)	5/40 (12. 5)	2/35(5.7)	3/38(7.9)	1/30(3.3)
Statistical analysis				
Peto test	P. a cons			
Standard method(d)	P = 0.8835			
Prevalence method(d)	P = 0.7038			
Combined analysis(d) Cochran-Armitage test(e)	P = 0.8843			
Fisher Exact test(e)	P = 0.2044	D = 0.0000	D 0.000	
113Her DAGCE CEST(E)		P = 0.2883	P = 0.3929	P = 0.1168

(HPT360A)

STUDY No. : 0417 NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANIMAL : RAT F344/DuCrj SEX : MALE

EX : MALE				PA	GE: 6
Group Name	Control	25ppm	100ppm	400ppm	
	SITE : thyroid				
	TUMOR : C-cell adenoma				
Tumor rate					
Overall rates(a)	8/50 (16. 0)	4/50(8.0)	4/50(8.0)	3/50(6.0)	
Adjusted rates(b)	20.00	10. 81	10.00	10.00	
Terminal rates(c) Statistical analysis Peto test	8/40(20.0)	3/35(8.6)	3/38(7.9)	3/30(10.0)	
Standard method(d)	P =				
Prevalence method(d)	P = 0.8725				
Combined analysis(d)	P =				
Cochran-Armitage test(e)	P = 0.2300				
Fisher Exact test(e)		P = 0. 1783	P = 0.1783	P = 0.0999	
	SITE : thyroid TUMOR : C-cell carcinoma				
Tumor rate					
Overall rates(a)	0/50(0.0)	3/50(6.0)	0/50(0.0)	1/50(2.0)	
Adjusted rates(b)	0.0	7.32	0.0	3. 23	
Terminal rates(c)	0/40(0.0)	2/35(5.7)	0/38(0.0)	0/30(0.0)	
Statistical analysis Peto test			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	5,00(0.0)	
Standard method(d)	P =				
Prevalence method(d)	P = 0.5232				
Combined analysis(d)	P =				
Cochran-Armitage test(e)	P = 0.8742				
Fisher Exact test(e)	A-24-	P = 0. 1212	P = N. C.	P = 0.5000	
_	SITE : thyroid TUMOR : C-cell adenoma, C-cell of	carcinoma			
Tumor rate	- ((
Overall rates(a)	8/50 (16. 0)	7/50(14.0)	4/50(8.0)	4/50(8.0)	
Adjusted rates(b)	20.00	17. 07	10.00	12. 90	
Terminal rates(c)	8/40(20.0)	5/35(14.3)	3/38(7.9)	3/30(10.0)	
Statistical analysis Peto test					
Standard method(d)	P =				
Prevalence method(d)	P = 0.8757				
Combined analysis(d)	P =				
Cochran-Armitage test(e)	P = 0.2409				
Fisher Exact test(e)	. 0.2100	P = 0.5000	P = 0.1783	P = 0 1700	
		1 0.0000	r = 0.1(03	P = 0.1783	

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

: RAT F344/DuCrj ANIMAL

SEX : MALE

PAGE: 7 Group Name Control 25ppm 100ppm 400ppm SITE : thyroid TUMOR : follicular adenoma, follicular adenocarcinoma Tumor rate Overall rates(a) 2/50(4.0) 1/50(2.0) 3/50(6.0) 2/50(4.0) Adjusted rates(b) 5.00 2.86 7.89 6.67 Terminal rates(c) 2/40(5.0) 1/35(2.9) 3/38(7.9) 2/30(6.7) Statistical analysis Peto test Standard method(d) P = -----Prevalence method(d) P = 0.3073Combined analysis(d) P = ----Cochran-Armitage test(e) P = 0.8652Fisher Exact test(e) P = 0.5000P = 0.5000P = 0.6913SITE : adrenal gland TUMOR : pheochromocytoma Tumor rate Overall rates(a) 3/50(6.0) 3/50(6.0) 3/50(6.0) 2/50(4.0) Adjusted rates(b) 7.50 8.33 7.89 4.76 Terminal rates(c) 3/40(7.5) 2/35(5.7) 3/38(7.9) 1/30(3.3) Statistical analysis Peto test Standard method(d) P = -----Prevalence method(d) P = 0.6816Combined analysis(d) P = -----Cochran-Armitage test(e) P = 0.6012Fisher Exact test(e) P = 0.6611P = 0.6611P = 0.5000SITE : adrenal gland TUMOR : pheochromocytoma:malignant Tumor rate Overall rates(a) 3/50(6.0) 1/50(2.0) 0/50(0.0) 0/50(0.0) Adjusted rates(b) 2.50 0.0 0.0 0.0 Terminal rates(c) 1/40(2.5) 0/35(0.0) 0/38(0.0) 0/30(0.0) Statistical analysis Peto test Standard method(d) P = 0.9389Prevalence method(d) P = 1.0000 ? Combined analysis(d) P = 0.9690Cochran-Armitage test(e) P = 0.1133Fisher Exact test(e) P = 0.3087P = 0.1212P = 0.1212

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NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANIMAL : RAT F344/DuCrj SEX : MALE

STUDY No. : 0417

Group Name	Control	25ppm	100ppm	400ppm
	SITE : adrenal gland			
umor rate	TUMOR : pheochromocytoma, pheochromo	cytoma:malignant		
Overall rates(a)	6/50(12.0)	4/50(8.0)	3/50(6.0)	0/50/ 4.0)
Adjusted rates(b)	10.00	8.33	7.89	2/50(4.0) 4.76
Terminal rates(c)	4/40(10.0)	2/35(5.7)	3/38(7.9)	1/30(3,3)
tatistical analysis	2, 25 (251 0)	2,000 0.17	0,00(1.0)	1/30(3.3/
Peto test				
Standard method(d)	P = 0.9389			
Prevalence method(d)	P = 0.7658			
Combined analysis(d)	P = 0.9054		·	
Cochran-Armitage test(e)	P = 0.1956			
Fisher Exact test(e)		P = 0.3703	P = 0.2435	P = 0.1343
	SITE : testis			A-10-40.
	TUMOR : interstitial cell tumor			
umor rate				
Overall rates(a)	45/50 (90.0)	39/50(78.0)	39/50(78.0)	42/50(84.0)
Adjusted rates(b)	97. 67	91.89	92. 11	96. 67
Terminal rates(c)	39/40 (97.5)	32/35(91.4)	35/38(92.1)	29/30 (96.7)
tatistical analysis				
Peto test				
Standard method(d)	P =			
Prevalence method(d)	P = 0.2120			
Combined analysis(d)	P =			
Cochran-Armitage test(e) Fisher Exact test(e)	P = 0.9825	D 0.0057	2 0 0000	
risher Exact test(e)		P = 0.0857	P = 0.0857	P = 0.2768
	OTMP			
	SITE : preputial/clitoral gland TUMOR : adenoma			
umor rate	romon - adenous			
Overall rates(a)	2/50(4.0)	1/50(2.0)	2/50(4.0)	4/50/ 0.0)
Adjusted rates(b)	5.00	2.86	2/50(4.0) 5.26	4/50(8.0)
Terminal rates(c)	2/40 (5. 0)	1/35(2.9)	2/38(5.3)	10. 00 3/30 (10. 0)
tatistical analysis	,	2,00(2.0)	2,00(0.0)	3/30(10.0)
Peto test				
Standard method(d)	P = 0.1369			
Prevalence method(d)	P = 0.1273			
Combined analysis(d)	P = 0.0527			
Cochran-Armitage test(e)	P = 0.1685			
Fisher Exact test(e)		P = 0.5000	P = 0.6913	P = 0.3389

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MEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANIMAL : RAT F344/DuCrj SEX : MALE

JUA · MALE

Group Name	Control		25ppm	100ppm	4	.00pm
	SITE : peritoneum					
Turner and the	TUMOR : mesothelioma					
Tumor rate	0/50/ 0.0	0 (70 (
Overall rates(a)	0/50(0.0)	2/50(7/50 (14.0)	1/50(2	. 0)
Adjusted rates(b)	0.0		5. 71	15. 79	(. 0
Terminal rates(c)	0/40(0.0)	2/35(5. 7)	6/38 (15. 8)	0/30(0	. 0)
Statistical analysis						
Peto test						
Standard method(d)	P = 0.1647					
Prevalence method(d)	P = 0.7322					
Combined analysis(d)	P = 0.5067					
Cochran-Armitage test(e)	P = 0.7409					
Fisher Exact test(e)		P = 0.24	75	P = 0.0062**	P = 0.5000	

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BAIS4

PAGE :

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

Standard method : Death analysis

Prevalence method: Incidental tumor test

Combined analysis: Death analysis + Incidental tumor test

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

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

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

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

APPENDIX O 2

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS,

RAT: FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANIMAL : RAT F344/DuCrj SEX : FEMALE

Group Name	Control	25ppm	100ppm	400ppm
	SITE : lung			
Tumor rate	TUMOR : bronchiolar-alveolar ade	enoma		
Overall rates(a)	1/50(2.0)	0/50(0.0)	1/50(2.0)	5/50(10.0)
Adjusted rates(b)	2. 63	0.0	2, 56	19. 23
Terminal rates(c) Statistical analysis	1/38(2.6)	0/45(0.0)	1/39(2.6)	5/26(19.2)
Peto test Standard method(d)	P =			
Prevalence method(d)	P = 0.0004**			
Combined analysis(d)	P =			
Cochran-Armitage test(e)	P = 0.0044**			
Fisher Exact test(e)		P = 0.5000	P = 0.7525	P = 0.1022
	SITE : spleen			
	TUMOR : mononuclear cell leukemi	.a		
Tumor rate				
Overall rates(a)	5/50(10.0)	3/50(6.0)	5/50(10.0)	13/50(26.0)
Adjusted rates(b)	7.89	4. 44	5. 13	19. 23
Terminal rates(c) Statistical analysis	3/38(7.9)	2/45(4.4)	2/39(5.1)	5/26(19.2)
Peto test				
Standard method(d)	P = 0.0055**			
Prevalence method(d)	P = 0.0147*			
Combined analysis(d)	P = 0.0004**			
Cochran-Armitage test(e)	P = 0.0018**			
Fisher Exact test(e)		P = 0.3575	P = 0.6297	P = 0.0332*
	SITE : liver			
	TUMOR : hepatocellular adenoma			
Tumor rate	1 (70 (0 0)			
Overall rates(a) Adjusted rates(b)	1/50(2.0)	0/50(0.0)	2/50(4.0)	32/50(64.0)
Adjusted rates(b) Terminal rates(c)	2. 63 1/38(2. 6)	0.0 0/45(0.0)	5. 13	80.77
Statistical analysis Peto test	1,00(2.0)	0/40(0.0)	2/39(5.1)	21/26(80.8)
Standard method(d)	P =			
Prevalence method(d)	P < 0.0001**?			
Combined analysis(d)	P =			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.5000	P = 0.5000	P < 0.0001**

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

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BAIS4

ANIMAL : RAT F344/DuCrj

SEX : FEMALE

(HPT360A)

Group Name Control 25ppm 100ppm 400ppm SITE : liver TUMOR : hemangiosarcoma Tumor rate Overall rates(a) 0/50(0.0) 0/50(0.0) 0/50(0.0) 6/50(12.0) Adjusted rates(b) 0.0 0.0 0.0 0.0 Terminal rates(c) 0/38(0.0) 0/45(0.0) 0/39(0.0) 0/26(0.0) Statistical analysis Peto test Standard method(d) P < 0.0001**? Prevalence method(d) P = ----Combined analysis(d) P < 0.0001**? Cochran-Armitage test(e) P < 0.0001** Fisher Exact test(e) P = N.C.P = N.C.P = 0.0133*SITE : liver TUMOR : hepatocellular carcinoma Tumor rate Overall rates(a) 0/50(0.0)0/50(0.0) 0/50(0.0) 38/50 (76.0) Adjusted rates(b) 0.0 0.0 0.0 90.91 Terminal rates(c) 0/38(0.0) 0/45(0.0)0/39(0.0) 23/26 (88.5) Statistical analysis Peto test Standard method(d) P = 0.0008**?Prevalence method(d) P < 0.0001**? Combined analysis(d) P < 0.0001**? Cochran-Armitage test(e) P < 0.0001** Fisher Exact test(e) P = N.C.P = N.C.P < 0.0001** SITE : liver TUMOR : hemangioma, hemangiosarcoma Tumor rate Overall rates(a) 0/50(0.0) 0/50(0.0) 0/50(0.0) 7/50(14.0) Adjusted rates(b) 0.0 0.0 0.0 3.85 Terminal rates(c) 0/38(0.0) 0/45(0.0) 0/39(0.0) 1/26(3.8) Statistical analysis Peto test Standard method(d) P < 0.0001**? Prevalence method(d) P = 0.0989Combined analysis(d) P < 0.0001**? Cochran-Armitage test(e) P < 0.0001** Fisher Exact test(e) P = N.C.P = N.C.P = 0.0062**

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANIMAL : RAT F344/DuCrj

SEX : FEMALE

Group Name	Control	25ppm	100ppm	400ррш
	SITE : liver			
Tumor rate	TUMOR : hepatocellular adenoma, l	nepatocellular carcinoma		
Overall rates(a)	1/50(2.0)	0/50(0.0)	0 (50 (4.0)	10 /50 / 00 0
Adjusted rates(b)	2. 63	0,50(0.0)	2/50(4.0)	43/50 (86. 0)
Terminal rates(c)	1/38(2.6)	0/45(0.0)	5. 13 2/39 (5. 1)	95. 12 24/26(92. 3)
Statistical analysis	1,00(2.0)	0,43(0.0)	2/39(0.1)	24/20(92.3)
Peto test				
Standard method(d)	P = 0.0008**?			
Prevalence method(d)	P < 0.0001**?			
Combined analysis(d)	P < 0.0001**?			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.5000	P = 0.5000	P < 0.0001**
,	SITE : pituitary gland			
	TUMOR : adenoma			
fumor rate	0 (50 (+0 0)	- (()		
Overall rates(a)	9/50 (18. 0)	9/50 (18. 0)	9/50(18.0)	6/50 (12.0)
Adjusted rates(b)	10. 53	18. 37	13.64	17. 86
Terminal rates(c)	4/38(10.5)	8/45(17.8)	5/39(12.8)	4/26(15.4)
Statistical analysis				
Peto test Standard method(d)	B - 0 901E			
Prevalence method(d)	P = 0.8015 P = 0.4972			
Combined analysis(d)	P = 0.4972 P = 0.6897			
Cochran-Armitage test(e)	P = 0.3355			
Fisher Exact test(e)	P - 0. 3395	B = 0.6094	D 0 0004	
Tioner LAGCE test(e)		P = 0.6024	P = 0.6024	P = 0. 2883
	SITE : pituitary gland			
	TUMOR : adenoma, adenocarcinoma			
fumor rate				
Overall rates(a)	10/50(20.0)	9/50(18.0)	9/50(18.0)	6/50(12.0)
Adjusted rates(b)	13. 16	18. 37	13. 64	17. 86
Terminal rates(c)	5/38(13.2)	8/45(17.8)	5/39(12.8)	4/26 (15.4)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.8015			
Prevalence method(d)	P = 0.5621			
Combined analysis(d)	P = 0.7353			
Cochran-Armitage test(e)	P = 0.2684			
Fisher Exact test(e)		P = 0.5000	P = 0.5000	P = 0.2070

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NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANIMAL : RAT F344/DuCrj SEX : FEMALE

Group Name	Control	25ppm	100ppm	400ppm	
	SITE : thyroid				
	TUMOR : C-cell adenoma				
umor rate					
Overall rates(a)	6/50(12.0)	7/50(14.0)	7/50(14.0)	5/50(10.0)	
Adjusted rates(b)	15. 79	15. 56	15. 91	15. 38	
Terminal rates(c)	6/38(15.8)	7/45(15.6)	4/39(10.3)	4/26(15.4)	
tatistical analysis Peto test					
Standard method(d)	P =				
Prevalence method(d)	P = 0.5223				
Combined analysis(d)	P =				
Cochran-Armitage test(e)	P = 0.5860				
Fisher Exact test(e)		P = 0.5000	P = 0.5000	P = 0.5000	
umor rate Overall rates(a) Adjusted rates(b) Terminal rates(c) tatistical analysis Peto test Standard method(d) Prevalence method(d) Combined analysis(d) Cochran-Armitage test(e) Fisher Exact test(e)	7/50 (14. 0) 18. 42 7/38 (18. 4) P = P = 0. 6363 P = P = 0. 3884	8/50(16.0) 17.78 8/45(17.8) P = 0.5000	8/50 (16. 0) 18. 18 5/39 (12. 8) P = 0. 5000	5/50(10.0) 15.38 4/26(15.4) P = 0.3798	
	SITE : uterus TUMOR : endometrial stromal po	lyb			
Cumor rate	•				
Overall rates(a)	7/50(14.0)	6/50(12.0)	7/50(14.0)	7/50(14.0)	
Adjusted rates(b)	15. 79	13. 33	17. 95	17. 14	
Terminal rates(c)	6/38 (15.8)	6/45(13.3)	7/39(17.9)	4/26(15.4)	
tatistical analysis					
Peto test					
Standard method(d)	P =				
Prevalence method(d)	P = 0.2978				
Prevalence method(d) Combined analysis(d)	P =				
Prevalence method(d)		P = 0.5000	P = 0.6129	P = 0.6129	

(HPT360A)

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

ANIMAL : RAT F344/DuCrj

SEX : FEMALE

PAGE: 14 Group Name Control 25ppm 100ppm 400ppm SITE : mammary gland TUMOR : fibroadenoma Tumor rate Overall rates(a) 6/50(12.0) 9/50(18.0) 10/50(20.0) 3/50(6.0) Adjusted rates(b) 15, 79 20.00 21.74 11.54 Terminal rates(c) 6/38(15.8) 9/45(20.0) 8/39(20.5) 3/26(11.5) Statistical analysis Peto test Standard method(d) P = -----Prevalence method(d) P = 0.8586Combined analysis(d) P = -----Cochran-Armitage test(e) P = 0.1102Fisher Exact test(e) P = 0.2883P = 0.2070P = 0.2435SITE : preputial/clitoral gland TUMOR : adenoma Tumor rate Overall rates(a) 1/50(2.0) 3/50(6.0) 4/50(8.0) 3/50(6.0) Adjusted rates(b) 2,50 6.67 10.26 5. 13 Terminal rates(c) 0/38(0.0) 3/45(6.7) 4/39(10.3) 1/26(3.8) Statistical analysis Peto test Standard method(d) P = 0.1613Prevalence method(d) P = 0.4496Combined analysis(d) P = 0.2671Cochran-Armitage test(e) P = 0.6529Fisher Exact test(e) P = 0.3087P = 0.1811P = 0.3087

(HPT360A)

BAIS4

Standard method : Death analysis

Prevalence method: Incidental tumor test

Combined analysis: Death analysis + Incidental tumor test

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

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

⁽c): Observed tumor incidence at terminal kill.

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

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

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

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

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

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

APPENDIX P 1

HISTOPATHOLOGICAL FINDINGS:

METASTASIS OF TUMOR: SYMMARY,

RAT: MALE:

ALL ANIMALS

STUDY NO. : 0417 ANIMAL : RAT F

: RAT F344/DuCrj

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

ALL ANIMALS (0-105W)

Organ	Findings	Group Name No. of Animals on Study	Control 50	25ppm 50	100ppm 50	400ppm 50
(n						
{Respiratory	system)					
nasal cavit	leukemic cell infiltration		<50> 0	<50> 1	<50> 1	<50> 0
lung	leukemic cell infiltration		<50> 3	<50> 2	<50> 3	<50> 0
	metastasis:liver tumor		0	0	0	2
	metastasis:bone tumor		0	0	1	0
	metastasis:spleen tumor		0	1	0	0
	metastasis:zymbal gland tumor		0	0	1	0
	metastasis:epididymis tumor		0	0	0	1
(Hematopoieti	c system)					
one marrow	leukemic cell infiltration		<50> 2	<50> 0	<50> 1	<50> 0
ymph node	leukemic cell infiltration		<50> 0	<50> 3	<50> 1	<50> 0
	metastasis:spleen tumor		0	1	0	0
	metastasis:epididymis tumor		0	0	0	1
	metastasis:skin/appendage tumor		0	0	1	0
chymus	metastasis:epididymis tumor		<50> 0	<50> 0	<50> 0	<50>
spleen	metastasis:pancreas tumor		<50> 0	<50> 0	<50> 0	<50>
(a)	a: Number of animals examined at tb: Number of animals with lesion	ne site				

ANIMAL : RAT F344/DuCrj

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

ALL ANIMALS (0-105W)

Organ	Findings	Group Name No. of Animals on Study	Control 50	25ppm 50	100ppm 50	400ppm 50
Hematopoiet	tic system)					
pleen	metastasis:epididymis tumor		<50> 0	<50> 0	<50> 0	<50> 1
(Circulatory	y system}					
eart	metastasis:epididymis tumor		<50> 0	<50> 0	<50> 0	<50> 1
Digestive s	system)					
tomach	metastasis:pancreas tumor		<50> 0	<50> 0	<50> 0	<50> 1
iver	leukemic cell infiltration		<50> 3	<50> 2	<50> 3	<50> 0
	metastasis:pancreas tumor		0	0	0	1
	metastasis:spleen tumor		1	1	0	0
	metastasis:small intestine tumor		0	0	1	0
ancreas	leukemic cell infiltration		<50> 0	<50> 2	<50> 0	<50> 0
	metastasis:spleen tumor		1	0	0	0
	metastasis:epididymis tumor		0 .	0	0	1
Urinary sys	stem}					
idney	leukemic cell infiltration		<50> 2	<50> 2	<50> 1	<50> 0
a > b	a : Number of animals examined at the s b : Number of animals with lesion	ite				

ANIMAL : RAT F344/DuCrj

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

ALL ANIMALS (0-105W)

Organ		Group Name Control No. of Animals on Study 50	25ppm 50	100ррш 50	400ppm 50
{Endocrine sy	ystem)				
pituitary	leukemic cell infiltration	<50> 0	<50> 1	<50> 0	<50> 0
adrenal	leukemic cell infiltration	<50> 0	<50> 0	<50> 1	<50> 0
{Reproductive	e system}				
semin ves	metastasis:epididymis tumor	<50> 0	<50> 0	<50> 0	<50> 1
prostate	leukemic cell infiltration	<50> 0	<50> 1	<50> 0	<50> 0
{Nervous syst	tem}				
brain	leukemic cell infiltration	<50> 1	<50> 1	<50> 1	<50> 0
	metastasis:pituitary tumor	1	0	0	0
spinal cord	leukemic cell infiltration	<50> 1	<50> 1	<50> 0	<50> 0
{Body cavitie	es)				
peritoneum	metastasis:pancreas tumor	<50> 0	<50> 0	<50> 0	<50> 1
	metastasis:spleen tumor	1	0	0	0
	metastasis:small intestine tumor	0	0	1	0
< a >	a: Number of animals examined at the si b: Number of animals with lesion	te			

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)

ALL ANIMALS (0-105W)

SEX : MALE

PAGE: 4

Organ		Group Name No. of Animals on Study	Control 50	25ppm 50	100ppm 50	400ppm 50
{Body cavities	s}					
retroperit			<50>	<50>	< 50>	<50>
	metastasis:epididymis tumor		0	0	0	1
mesenterium			<50>	<50>	<50>	<50≻
	metastasis:epididymis tumor		0	0	0	1
dipose			<50>	<50>	<50>	<50>
	metastasis:pancreas tumor		0	0	0	1
(a)	a : Number of animals examined at the si	te				
b	b : Number of animals with lesion					
(JPT150)						

APPENDIX P 2

HISTOPATHOLOGICAL FINDINGS:

METASTASIS OF TUMOR: SYMMARY,

RAT: MALE:

DEAD AND MORIBUND ANIMALS

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

PAGE: 1 Group Name Control 25ppm 100ppm 400ppm No. of Animals on Study 10 15 12 Organ____ Findings_ {Respiratory system} nasal cavit <10> <15> <12> ⟨20⟩ leukemic cell infiltration 0 1 1 0 lung <10> <15> <12> ⟨20⟩ leukemic cell infiltration 2 2 2 metastasis:liver tumor metastasis:bone tumor metastasis:spleen tumor metastasis:epididymis tumor 0 {Hematopoietic system} bone marrow <10> <15> <12> ⟨20⟩ leukemic cell infiltration 1 lymph node <10> <15> <12> <20> leukemic cell infiltration 0 2 metastasis:spleen tumor 0 metastasis:epididymis tumor 0 metastasis:skin/appendage tumor 0 1 thymus <10> <15> <12> (20) metastasis:epididymis tumor 0 0 0 spleen <10> <15> <12> (20) metastasis:epididymis tumor {Circulatory system} heart <10> <15> <12> <20> metastasis:epididymis tumor 0 0 1

 $[\]langle$ a \rangle a : Number of animals examined at the site

b b: Number of animals with lesion

ANIMAL

: RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE

HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

Group Name Control 25ppm 100ppm 400ppm No. of Animals on Study 10 20 Organ____ Findings__ (Digestive system) liver <10> <15> <12> <20> leukemic cell infiltration 2 2 2 0 metastasis:spleen tumor 1 0 metastasis:small intestine tumor 0 0 1 pancreas <10> <15> <12> <20> leukemic cell infiltration 2 0 metastasis:spleen tumor metastasis:epididymis tumor 0 {Urinary system} kidney <10> <15> <12> ⟨20⟩ leukemic cell infiltration 2 {Endocrine system} pituitary <10> <15> <12> <20> leukemic cell infiltration 0 adrenal <10> <15> <12> <20> leukemic cell infiltration 0 {Reproductive system} semin ves <10> <15> <12> ⟨20⟩

0

<10>

0

0

<15>

1

<12>

0

leukemic cell infiltration

metastasis:epididymis tumor

b: Number of animals with lesion

prostate

1

<20>

0

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

ANIMAL : RAT F344/DuCrj

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

DEAD AND MORIBUND ANIMALS (0-105W)

PAGE: 3

Organ		Group Name Control No. of Animals on Study 10	25ppm 15	100ppm 12	400ppm 20
<u> </u>					
Nervous syste	em}				
orain	leukemic cell infiltration	<10> 1	<15> 1	<12>	<20> 0
	metastasis:pituitary tumor	1	0	0	0
spinal cord	leukemic cell infiltration	<10> 1	<15> 1	<12> 0	<20> 0
Body cavities	s}				
eritoneum	metastasis:spleen tumor	<10>	<15> 0	<12> 0	<20> 0
	metastasis:small intestine tumor	0	0	1	0
etroperit	metastasis:epididymis tumor	<10> 0	<15> 0	<12> 0	<20> 1
nesenterium	metastasis:epididymis tumor	<10> 0	<15> 0	<12> 0	<20>
a > b	a: Number of animals examined at the si b: Number of animals with lesion	te			

(JPT150)

APPENDIX P 3

HISTOPATHOLOGICAL FINDINGS:

METASTASIS OF TUMOR: SYMMARY,

RAT: MALE:

SACRIFICED ANIMALS

ANIMAL

: RAT F344/DuCrj

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

SACRIFICED ANIMALS (105W)

PAGE: 1 Group Name Control 25ppm 100ppm 400ppm No. of Animals on Study Findings_ Organ____ {Respiratory system} lung <40> <35> <38> <30> leukemic cell infiltration 1 0 metastasis:liver tumor 0 metastasis:zymbal gland tumor 0 0 {Hematopoietic system} bone marrow <40> <35> <38> <30> leukemic cell infiltration 0 lymph node <40> <35> <38> <30> leukemic cell infiltration 0 0 spleen <40> <35> <38> <30> metastasis:pancreas tumor {Digestive system} stomach <40> <35> <38> ⟨30⟩ metastasis:pancreas tumor 0 0 0 liver <40> <35> <38> <30> leukemic cell infiltration 1 0 0 metastasis:pancreas tumor 0 0 1 {Body cavities} peritoneum <40> <35> <38> <30> metastasis:pancreas tumor 0 0 0 1 a: Number of animals examined at the site <a>> b b: Number of animals with lesion

(JPT150)

ANIMAL : RAT F344/DuCrj

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

SACRIFICED ANIMALS (105W)

organ		Group Name No. of Animals on Study	Control 40	25ррш 35	100ppm 38	400ppm 30
Body cavities	s)					
dipose	metastasis:pancreas tumor		<40> 0	<35> 0	<38> 0	<30>

APPENDIX P 4

HISTOPATHOLOGICAL FINDINGS:

METASTASIS OF TUMOR: SYMMARY,

RAT: FEMALE:

ALL ANIMALS

ANIMAL

: RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)

ALL ANIMALS (0-105W)

PAGE: 5 Group Name Control 25ppm 100ppm 400ppm No. of Animals on Study Organ____ Findings__ {Respiratory system} lung <50> <50> ⟨50⟩ <50> leukemic cell infiltration 6 metastasis:liver tumor 14 metastasis:bone tumor 1 {Hematopoietic system} bone marrow <50> <50> <50> <50> leukemic cell infiltration 2 4 lymph node <50> <50> <50> <50> leukemic cell infiltration 1 0 2 spleen <50> ⟨50⟩ <50> <50> leukemic cell infiltration {Circulatory system} heart <50> <50> <50> <50> leukemic cell infiltration {Digestive system} stomach <50> <50> <50> <50> leukemic cell infiltration 0 liver <50> <50> <50> <50> leukemic cell infiltration 6 2 3 10 pancreas <50> <50> ⟨50⟩ <50> leukemic cell infiltration 0 2 1 (a)

b

a: Number of animals examined at the site

b: Number of animals with lesion

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)

PAGE: 6

ALL ANIMALS (0-105W)

an		oup Name . of Animals on Study	Control 50	25ppm 50	100ppm 50	400ppm 50
inary syst	em}					
iney	leukemic cell infiltration		<50> 2	<50> 0	<50> 1	<50> 1
ndocrine sy	stem}					
tuitary	leukemic cell infiltration		<50> 0	<50> 1	<50> 2	<50> 0
renal	leukemic cell infiltration		<50> 1	<50> 1	<50> 2	<50> 1
	metastasis:liver tumor		0	0	0	1
ervous syst	em}					
ain	leukemic cell infiltration		<50> 1	<50> 0	<50> 0	<50> 1
	metastasis:pituitary tumor		1	0	0	0
nal cord	leukemic cell infiltration		<50> 1	<50> 0	<50> 0	<50> 0
pecial sens	e organs/appendage}					
e	leukemic cell infiltration		<50> 0	<50> 0	<50> 1	<50> 0
der gl	leukemic cell infiltration		<50> 1	<50> 0	<50> 0	<50> 0
ısculoskele	tal system)					
scle	leukemic cell infiltration		<50> 1	<50> 0	<50> 0	<50> 0
a > b	a: Number of animals examined at the siteb: Number of animals with lesion					

APPENDIX P 5

HISTOPATHOLOGICAL FINDINGS:

METASTASIS OF TUMOR: SYMMARY,

RAT: FEMALE:

DEAD AND MORIBUND ANIMALS

ANIMAL

: RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

PAGE: 4 Group Name Control 25ppm 100ppm 400ppm No. of Animals on Study 24 Findings__ Organ____ {Respiratory system} lung <12> < 5> <11> <24> leukemic cell infiltration 2 metastasis:liver tumor 0 metastasis:bone tumor 0 {Hematopoietic system} bone marrow <12> < 5> <11> <24> leukemic cell infiltration 0 2 lymph node <12> < 5> <11> <24> leukemic cell infiltration 1 2 spleen <12> < 5> <11> <24> leukemic cell infiltration {Circulatory system} heart <12> < 5> <11> ⟨24⟩ leukemic cell infiltration {Digestive system} stomach <12> < 5> <11> <24> leukemic cell infiltration 0 1 liver <12> < 5> <11> ⟨24⟩ leukemic cell infiltration 3 2 7 pancreas <12> < 5> <11> <24> leukemic cell infiltration 1 0 2 1 < a > a: Number of animals examined at the site b b: Number of animals with lesion

(JPT150)

ANIMAL

: RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

PAGE: 5 Group Name Control 25ppm 100ppm 400ppm No. of Animals on Study Organ____ Findings_ {Urinary system} kidney <12> < 5> <11> <24> leukemic cell infiltration 1 1 {Endocrine system} pituitary <12> < 5> <11> (24) leukemic cell infiltration 0 2 0 adrenal <12> < 5> <11> ⟨24⟩ leukemic cell infiltration 1 (Nervous system) brain <12> < 5> <11> <24> leukemic cell infiltration 1 0 1 spinal cord <12> < 5> ⟨11⟩ <24> leukemic cell infiltration 1 {Special sense organs/appendage} eye <12> < 5> <11> (24) leukemic cell infiltration 0 0 Harder gl <12> < 5> <11> (24) leukemic cell infiltration 1 0 0 {Musculoskeletal system} muscle <12> < 5> <11> <24> leukemic cell infiltration 1 0 0 0 < a > a: Number of animals examined at the site b b: Number of animals with lesion

(JPT150)

APPENDIX P 6

HISTOPATHOLOGICAL FINDINGS:

METASTASIS OF TUMOR: SYMMARY,

RAT: FEMALE:

SACRIFICED ANIMALS

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 : FEMALE HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)

SACRIFICED ANIMALS (105W)

PAGE: 3 Group Name Control 25ppm 100ppm 400ppm No. of Animals on Study Findings_ Organ____ {Respiratory system} lung <38> <45> <39> <26> leukemic cell infiltration 0 1 2 metastasis:liver tumor 0 0 0 {Hematopoietic system} bone marrow <38> <45> <39> <26> leukemic cell infiltration 1 0 0 lymph node <38> <45> <39> <26> leukemic cell infiltration 0 {Digestive system} liver ⟨38⟩ <45> <39> <26> leukemic cell infiltration {Endocrine system} adrenal <38> <45> <39> <26> metastasis:liver tumor (Nervous system) brain <38> <45> <39> <26> metastasis:pituitary tumor < a > a: Number of animals examined at the site b b: Number of animals with lesion (JPT150)

APPENDIX Q

METHODS, UNITS AND DECIMAL PLACEFOR
HEMATOLOGY AND BIOCHEMISTRY
IN THE 2-YEAR INHALATION STUDY OF
1-BROMO-3-CHLOROPROPANE

METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-YEAR INHALATION STUDY OF 1-BROMO-3-CHLOROPROPANE

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