酢酸イソプロピルのラットを用いた
吸入による2週間毒性試験報告書

試験番号：0551

APPENDICES

APPENDICES

APPENDICES (CONTINUED)

APPENDIX A 1

IDENTITY AND IMPURITY OF ISOPROPYL ACETATE IN THE 2-WEEK INHALATION STUDY

IDENTITY AND IMPURITY OF ISOPROPYL ACETATE IN THE 2-WEEK INHALATION STUDY

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

Lot No. : KLR6631

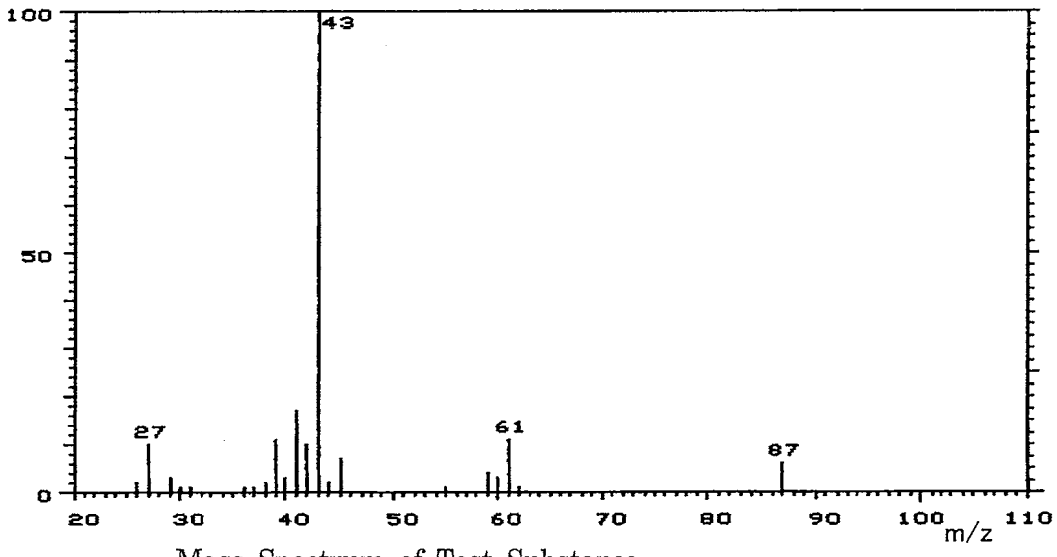
1. Spectral Data

Mass Spectrometry

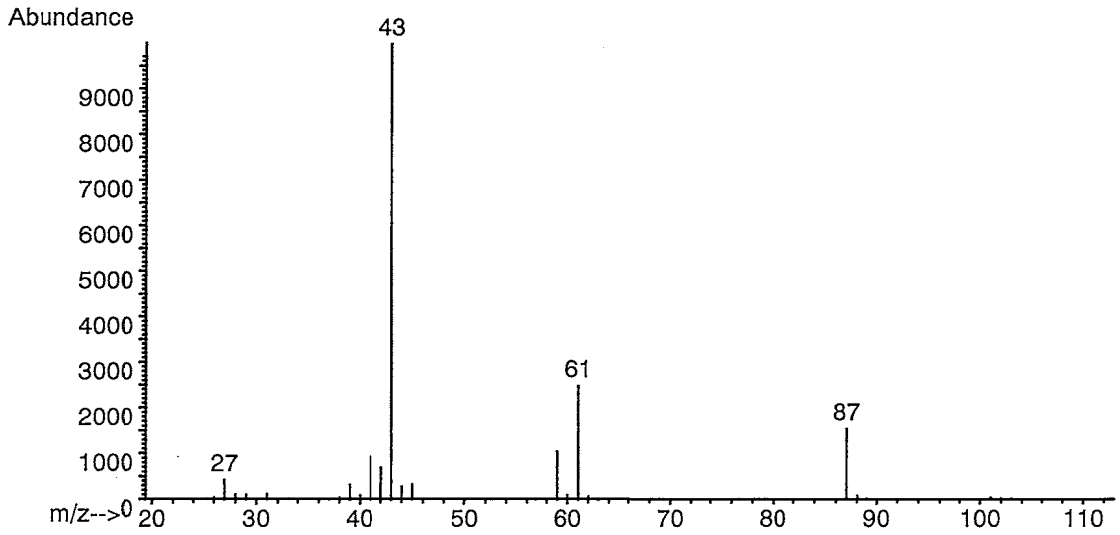
Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance



Mass Spectrum of Literature Data*

Result: The mass spectrum was consistent with literature spectrum.

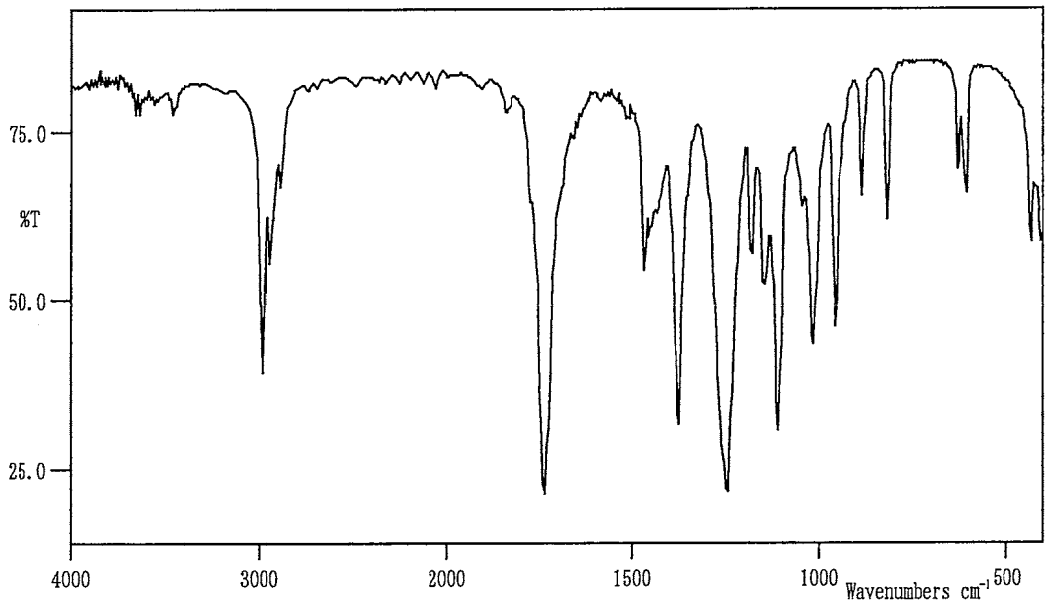
(*McLafferty FW, ed. 1994. Wiley Registry of Mass Spectral Data. 6th ed. New York, NY:John Wiley and Sons.)

Infrared Spectrometry

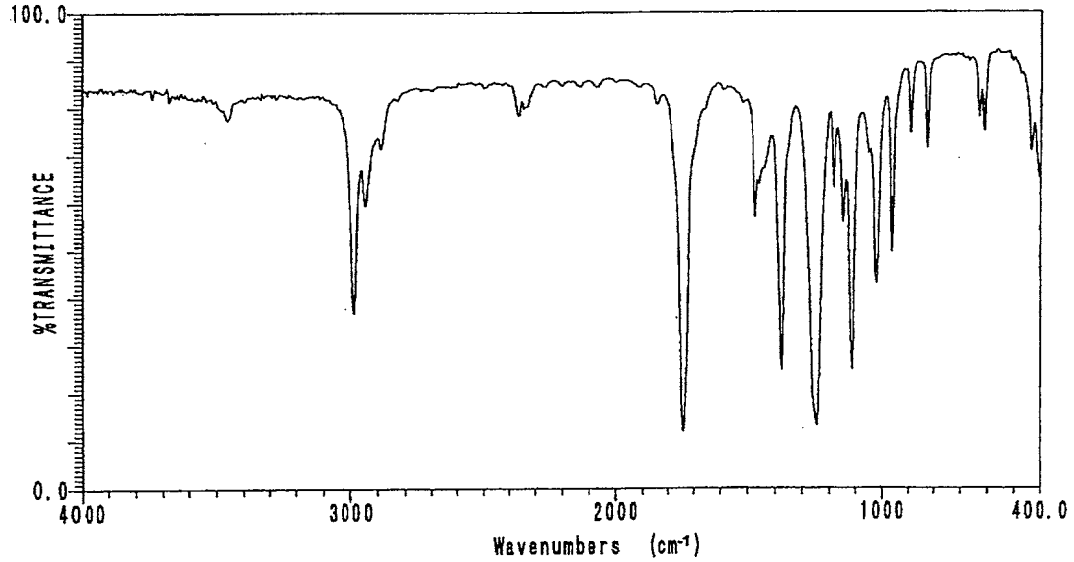
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 4 cm^{-1}



Infrared Spectrum of Test Substance



Infrared Spectrum of Literature Data*

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 mmϕ × 60 m)

Column Temperature: 80° C

Flow Rate : 15 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μL

Sample Name	Peak No.	Area (%)	Peak Name
Test Substance	1	0.040	2-Propanol
	2	99.960	Isopropyl acetate

Result: Gas chromatography indicated one major peak (peak No. 2) and one impurity. The impurity (peak No. 1) was identified as 2-propanol by comparing GC-MS with that of standard sample. The amount of 2-propanol in the test substance was 0.040% (The quantity value by the standard sample was 0.040%.) with a gas chromatograph.

3. Conclusion: The test substance was identified as isopropyl acetate by mass spectrum and infrared spectrum. Gas chromatography indicated one major peak (isopropyl acetate) and one impurity. The impurity was 2-propanol in the test substance.

APPENDIX A 2

STABILITY OF ISOPROPYL ACETATE IN THE 2-WEEK INHALATION STUDY

STABILITY OF ISOPROPYL ACETATE IN THE 2-WEEK INHALATION STUDY

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

Lot No. : KLR6631

1. Sample : This lot was used from 2004.9.28 to 2004.10.11. 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 mmϕ × 60 m)

Column Temperature: 80° C

Flow Rate : 15 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μL

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
2004.09.24	1	1.927	0.040
	2	3.917	99.960
2004.10.15	1	1.908	0.032
	2	3.903	99.968

Result: Gas chromatography indicated one major peak (peak No.2) and one impurity (peak No. 1 < 0.1% of total area) analyzed on 2004.9.24 and one major peak (peak No.2) and one impurity (peak No. 1 < 0.1% of total area) analyzed on 2004.10.15. No new trace impurity peak in the test substance analyzed on 2004.10.15 was detected.

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

APPENDIX B 1

CONCENTRATION OF ISOPROPYL ACETATE IN THE INHALATION CHAMBER OF THE 2-WEEK INHALATION STUDY

CONCENTRATION OF ISOPROPYL ACETATE IN THE INHALATION CHAMBER OF THE 2-WEEK INHALATION STUDY

Group Name	Concentration(ppm) Mean ± S.D.
Control	0.0 ± 0.0
500 ppm	499.1 ± 2.4
1000 ppm	998.4 ± 5.5
2000 ppm	2000.1 ± 13.2
4000 ppm	3988.9 ± 22.2
8000 ppm	7979.6 ± 48.5

APPENDIX B 2

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 2-WEEK INHALATION STUDY OF ISOPROPYL ACETATE

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 2-WEEK INHALATION STUDY OF ISOPROPYL ACETATE

Group Name	Temperature (℃) Mean ± S.D.	Humidity (%) Mean ± S.D.	Ventilation Rate (L/min) Mean ± S.D.	Air Change (time/h) Mean
Control	22.4 ± 0.1	56.8 ± 0.3	213.3 ± 0.8	12.1
500 ppm	22.4 ± 0.1	56.4 ± 0.9	213.3 ± 0.7	12.1
1000 ppm	22.3 ± 0.1	56.6 ± 1.3	213.2 ± 0.7	12.1
2000 ppm	22.3 ± 0.1	56.1 ± 1.6	213.5 ± 0.8	12.1
4000 ppm	22.3 ± 0.1	54.0 ± 2.1	213.0 ± 0.6	12.1
8000 ppm	22.3 ± 0.2	53.6 ± 2.8	213.1 ± 0.6	12.1

APPENDIX C 1

CLINICAL OBSERVATION : SUMMARY, RAT : MALE

(2-WEEK STUDY)

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Administration Week-day												
		1-1	1-2	1-2	1-3	1-4	1-4	1-7	1-7	2-1	2-2	2-3	2-4	2-4	2-7
		2	1	2	2	1	2	1	2	2	2	2	1	2	1
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	5	0	5	5	0	5	0	5	5	5	5	0	5	0
PRONE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	1	0	0	2	0	0	0	0	0	0	0	0	0	0
LATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	4	0	5	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	0	0	0	3	0	5	0	5	5	5	5	0	5	0
TOUCH-RESPONSE. DISAPPEAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	5	0	5	5	0	5	0	5	5	5	5	0	5	0
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	0	0	0	0	0	5	0	5	5	5	5	5	5	5

Clinical sign	Group Name	Administration Week-day 2-7 2
LOCOMOTOR MOVEMENT DECR	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	5
PRONE	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	0
LATERAL	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	0
HUNCHBACK POSITION	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	5
TOUCH-RESPONSE. DISAPPEAR	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	5
PILOERECTION	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	5

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Administration Week-day 1-1 2	1-2 1	1-2 2	1-3 2	1-4 1	1-4 2	1-7 1	1-7 2	2-1 2	2-2 2	2-3 2	2-4 1	2-4 2	2-7 1
LACRIMATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	3	0	5	5	0	5	0	2	0	0	0	0	0	0
GUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	0	2	0	0	0	0	0	0	0	0	0	0	0	0
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	0	0	0	0	0	0	0	2	2	2	2	2	2	2
REDDENING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	0	0	0	0	0	0	0	0	0	5	5	0	5	0
BRADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	5	0	5	5	0	5	0	5	5	5	5	0	5	0

Clinical sign	Group Name	Administration Week-day 2-7 2
LACRIMATION	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	2
GUM	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	0
CORNEAL OPACITY	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	3
REDDENING	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	5
BRADYPNEA	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	5

APPENDIX C 2

CLINICAL OBSERVATION : SUMMARY, RAT : FEMALE

(2-WEEK STUDY)

Clinical sign	Group Name	Administration Week-day 1-1 2	1-2 1	1-2 2	1-3 2	1-4 1	1-4 2	1-7 1	1-7 2	2-1 2	2-2 2	2-3 2	2-4 1	2-4 2	2-7 1
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	5	0	5	5	0	4	0	5	5	5	5	0	5	0
PRONE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	5	0	3	3	0	0	0	0	0	0	0	0	0	0
LATERAL	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	0	0	1	0	0	0	0	0	0	0	0	0	0	0
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	0	0	1	1	0	5	0	5	5	5	5	0	5	0
TOUCH-RESPONSE. DISAPPEAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	5	0	5	5	0	5	0	5	5	5	5	0	5	0
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	0	0	0	0	0	5	0	5	5	5	5	5	5	5

Clinical sign	Group Name	Administration Week-day 2-7 2
LOCOMOTOR MOVEMENT DECR	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	5
PRONE	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	0
LATERAL	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	1
HUNCHBACK POSITION	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	4
TOUCH-RESPONSE. DISAPPEAR	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	5
PILOERECTION	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	5

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Administration Week-day 1-1 2	1-2 1	1-2 2	1-3 2	1-4 1	1-4 2	1-7 1	1-7 2	2-1 2	2-2 2	2-3 2	2-4 1	2-4 2	2-7 1
LACRIMATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	0	0	5	5	0	5	0	4	0	0	0	0	0	0
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	0	0	0	0	0	0	2	3	3	4	4	4	4	4
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BRADYPNEA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	500ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8000ppm	5	0	5	5	0	5	0	5	5	5	5	0	5	0

Clinical sign	Group Name	Administration Week-day 2-7 2
LACRIMATION	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	4
CORNEAL OPACITY	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	4
RESPIRATORY SOUND ABNOR	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	1
BRADYPNEA	Control	0
	500ppm	0
	1000ppm	0
	2000ppm	0
	4000ppm	0
	8000ppm	5

APPENDIX D 1

BODY WEIGHT CHANGES : SUMMARY, RAT : MALE

(2-WEEK STUDY)

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
UNIT : g
REPORT TYPE : A1 2
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day 0-0	1-2	1-4	1-7	2-4	2-7
Control	115± 5	120± 4	123± 4	133± 2	144± 4	154± 4
500ppm	115± 5	117± 6	120± 6	128± 7	140± 8	148± 8
1000ppm	115± 4	119± 5	122± 4	132± 4	143± 4	153± 6
2000ppm	114± 5	117± 5	124± 5	135± 6	148± 7	160± 8
4000ppm	115± 5	115± 5	121± 6	136± 7	150± 9	166± 9
8000ppm	115± 4	104± 4**	103± 5**	115± 6**	122± 8**	139± 7*

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX D 2

BODY WEIGHT CHANGES : SUMMARY, RAT : FEMALE

(2-WEEK STUDY)

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
UNIT : g
REPORT TYPE : A1 2
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day 0-0	1-2	1-4	1-7	2-4	2-7
Control	91± 3	92± 3	95± 4	98± 3	103± 3	108± 4
500ppm	91± 4	94± 6	96± 6	100± 7	106± 7	111± 8
1000ppm	91± 4	93± 4	95± 5	100± 5	104± 5	109± 4
2000ppm	91± 3	92± 5	93± 6	99± 6	105± 7	111± 8
4000ppm	91± 4	91± 6	93± 6	101± 7	105± 8	114± 9
8000ppm	91± 4	84± 4*	84± 4*	91± 4	93± 5	103± 5

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX E 1

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : MALE

(2-WEEK STUDY)

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
UNIT : g
REPORT TYPE : A1 2
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration 1-7(6)	week-day(effective) 2-7(7)
Control	13.5± 0.5	14.0± 1.2
500ppm	13.6± 1.2	13.9± 1.5
1000ppm	14.0± 0.6	14.5± 1.7
2000ppm	13.6± 0.5	14.0± 0.3
4000ppm	13.3± 1.0	14.5± 0.8
8000ppm	9.0± 1.0**	11.8± 1.0*

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX E 2

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : FEMALE

(2-WEEK STUDY)

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
UNIT : g
REPORT TYPE : A1 2
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day(effective) 1-7(6)	2-7(7)
Control	10.7± 0.4	10.5± 0.5
500ppm	11.8± 1.2	10.8± 1.1
1000ppm	11.1± 0.8	10.1± 0.5
2000ppm	11.2± 1.0	10.5± 1.1
4000ppm	10.7± 1.0	10.9± 0.8
8000ppm	7.9± 0.4**	9.6± 0.5

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX F 1

HEMATOLOGY : SUMMARY,
RAT : MALE

(2-WEEK STUDY)

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (3W)

Group Name	NO. of Animals	RED BLOOD CELL $10^6/\mu\ell$	HEMOGLOBIN g/dℓ	HEMATOCRIT %	MCV f ℓ	MCH p g	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
Control	5	8.60± 0.18	16.4± 0.3	45.1± 0.8	52.4± 0.4	19.1± 0.3	36.4± 0.6	774± 33
500ppm	5	8.59± 0.18	16.4± 0.2	44.9± 0.4	52.3± 0.8	19.2± 0.3	36.6± 0.4	738± 54
1000ppm	5	8.59± 0.25	16.4± 0.4	45.1± 1.1	52.4± 0.6	19.1± 0.4	36.4± 0.7	743± 24
2000ppm	5	8.42± 0.16	16.1± 0.2	44.3± 0.9	52.6± 0.5	19.2± 0.2	36.5± 0.4	795± 61
4000ppm	5	8.29± 0.15	15.8± 0.3*	43.6± 0.3*	52.6± 1.0	19.1± 0.2	36.3± 0.6	803± 87
8000ppm	5	8.73± 0.22	16.5± 0.4	45.4± 1.1	52.0± 0.6	18.9± 0.1	36.3± 0.4	559± 44**

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

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (3W)

Group Name	NO. of Animals	RETICULOCYTE %		PROTHROMBIN TIME sec		APTT sec	
Control	5	2.0±	0.1	13.1±	0.8	21.1±	1.4
500ppm	5	1.8±	0.2	13.9±	1.4	22.2±	2.7
1000ppm	5	1.8±	0.1	15.0±	2.0	23.5±	1.3
2000ppm	5	2.4±	0.3*	13.0±	0.2	20.2±	1.6
4000ppm	5	2.8±	0.1**	13.0±	0.4	18.2±	1.4*
8000ppm	5	1.7±	0.1	13.6±	0.4	19.6±	0.5

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (3W)

Group Name	NO. of Animals	WBC $10^3/\mu\ell$	Differential WBC (%)
Control	5	4.12± 0.37	
500ppm	5	4.41± 1.02	
1000ppm	5	4.04± 1.02	
2000ppm	5	4.27± 0.50	
4000ppm	5	4.82± 0.91	
8000ppm	5	3.76± 0.58	

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX F 2

HEMATOLOGY : SUMMARY,
RAT : FEMALE

(2-WEEK STUDY)

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (3W)

Group Name	NO. of Animals	RED BLOOD CELL $10^6/\mu\ell$	HEMOGLOBIN g/dℓ	HEMATOCRIT %	MCV f ℓ	MCH p g	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
Control	5	9.02± 0.10	17.3± 0.2	46.9± 0.5	52.0± 0.4	19.2± 0.1	36.9± 0.3	602± 24
500ppm	5	8.95± 0.29	17.3± 0.4	46.5± 1.5	51.9± 0.5	19.3± 0.2	37.2± 0.7	683± 52
1000ppm	5	8.92± 0.29	17.2± 0.5	46.4± 1.6	52.0± 0.7	19.2± 0.3	36.9± 0.3	616± 71
2000ppm	5	8.73± 0.33	16.8± 0.7	45.3± 1.5	51.9± 0.4	19.2± 0.3	37.1± 0.7	669± 35
4000ppm	5	8.63± 0.21	16.7± 0.3	45.1± 1.3	52.2± 0.4	19.3± 0.3	37.0± 0.8	648± 44
8000ppm	5	8.83± 0.22	16.9± 0.4	45.9± 0.9	51.9± 0.3	19.2± 0.2	36.9± 0.5	470± 66**

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

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (3W)

Group Name	NO. of Animals	RETICULOCYTE %	PROTHROMBIN TIME sec	APTT sec
Control	5	1.1± 0.1	12.4± 0.7	19.3± 1.7
500ppm	5	1.2± 0.2	12.7± 0.4	17.4± 0.9
1000ppm	5	1.2± 0.2	12.5± 0.6	18.7± 1.5
2000ppm	5	1.2± 0.3	12.7± 0.4	17.5± 0.4
4000ppm	5	1.3± 0.1	13.0± 0.4	18.1± 1.3
8000ppm	5	1.2± 0.1	13.4± 0.4	18.6± 1.7

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

Group Name	NO. of Animals	WBC $10^3/\mu\ell$		Differential WBC (%)
Control	5	3.46±	1.36	
500ppm	5	3.71±	0.41	
1000ppm	5	3.50±	0.62	
2000ppm	5	3.18±	0.98	
4000ppm	5	3.24±	0.81	
8000ppm	5	3.31±	0.75	

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX G 1

BIOCHEMISTRY : SUMMARY,
RAT : MALE

(2-WEEK STUDY)

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (3W)

Group Name	NO. of Animals	TOTAL PROTEIN g/dℓ	ALBUMIN g/dℓ	A/G RATIO	T-BILIRUBIN mg/dℓ	GLUCOSE mg/dℓ	T-CHOLESTEROL mg/dℓ	TRIGLYCERIDE mg/dℓ
Control	5	5.7± 0.1	3.4± 0.0	1.5± 0.0	0.12± 0.01	143± 16	52± 7	26± 8
500ppm	5	5.5± 0.1	3.3± 0.1	1.5± 0.1	0.12± 0.02	135± 4	47± 5	20± 7
1000ppm	5	5.7± 0.1	3.4± 0.1	1.5± 0.0	0.11± 0.02	145± 6	50± 2	29± 9
2000ppm	5	5.7± 0.1	3.4± 0.2	1.5± 0.1	0.12± 0.01	137± 7	53± 3	21± 4
4000ppm	5	5.7± 0.1	3.3± 0.1	1.4± 0.1	0.12± 0.01	142± 11	58± 6	31± 6
8000ppm	5	5.8± 0.1	3.4± 0.0	1.4± 0.0	0.12± 0.02	188± 9**	57± 7	34± 5

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (3W)

Group Name	NO. of Animals	PHOSPHOLIPID mg/dℓ	AST IU/ℓ	ALT IU/ℓ	LDH IU/ℓ	ALP IU/ℓ	G-GTP IU/ℓ	CK IU/ℓ
Control	5	96± 12	70± 3	32± 0	229± 50	624± 36	0± 1	231± 9
500ppm	5	91± 10	76± 7	35± 3	213± 61	676± 60	1± 0	237± 36
1000ppm	5	94± 6	76± 7	36± 4	199± 61	664± 38	0± 1	253± 27
2000ppm	5	95± 6	69± 4	34± 3	201± 115	657± 39	1± 0	225± 34
4000ppm	5	97± 7	66± 5	32± 2	177± 35	648± 85	1± 0	222± 4
8000ppm	5	106± 9	67± 2	35± 1	215± 86	771± 48**	1± 0	231± 31

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (3W)

Group Name	NO. of Animals	UREA NITOROGEN mg/dℓ	CREATININE mg/dℓ	SODIUM mEq/ℓ	POTASSIUM mEq/ℓ	CHLORIDE mEq/ℓ	CALCIUM mg/dℓ	INORGANIC PHOSPHORUS mg/dℓ
Control	5	16.7± 2.7	0.5± 0.1	142± 1	3.5± 0.1	104± 1	10.1± 0.1	7.5± 0.3
500ppm	5	16.8± 1.4	0.5± 0.0	142± 1	3.5± 0.2	103± 1	10.0± 0.2	7.7± 0.4
1000ppm	5	16.4± 0.8	0.5± 0.1	142± 1	3.3± 0.1	102± 1	10.2± 0.1	7.9± 0.3
2000ppm	5	15.7± 1.1	0.5± 0.1	142± 1	3.5± 0.1	102± 2	10.2± 0.1	7.7± 0.4
4000ppm	5	14.8± 0.9	0.4± 0.0	141± 1	3.6± 0.1	101± 0*	10.4± 0.2	8.0± 0.7
8000ppm	5	12.9± 1.4**	0.5± 0.0	140± 1*	4.0± 0.4	100± 1**	10.4± 0.3	8.4± 1.0

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX G 2

BIOCHEMISTRY : SUMMARY,
RAT : FEMALE

(2-WEEK STUDY)

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (3W)

Group Name	NO. of Animals	TOTAL PROTEIN g/dℓ		ALBUMIN g/dℓ		A/G RATIO		T-BILIRUBIN mg/dℓ		GLUCOSE mg/dℓ		T-CHOLESTEROL mg/dℓ		TRIGLYCERIDE mg/dℓ	
Control	5	5.5±	0.1	3.3±	0.1	1.6±	0.1	0.13±	0.01	133±	16	76±	9	19±	9
500ppm	5	5.6±	0.2	3.4±	0.1	1.6±	0.1	0.13±	0.01	123±	19	67±	5	13±	4
1000ppm	5	5.4±	0.1	3.3±	0.1	1.5±	0.1	0.14±	0.01	132±	20	71±	9	15±	2
2000ppm	5	5.5±	0.1	3.3±	0.1	1.5±	0.1	0.13±	0.01	128±	11	72±	3	14±	4
4000ppm	5	5.5±	0.1	3.3±	0.1	1.5±	0.1	0.14±	0.02	124±	17	77±	4	13±	1
8000ppm	5	5.8±	0.1**	3.4±	0.1	1.4±	0.1	0.16±	0.04	173±	16**	77±	5	24±	2

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (3W)

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl	AST IU/l	ALT IU/l	LDH IU/l	ALP IU/l	G-GTP IU/l	CK IU/l
Control	5	134± 10	74± 5	32± 4	353± 189	534± 33	2± 0	278± 55
500ppm	5	122± 11	79± 6	33± 4	294± 155	579± 37	2± 1	246± 30
1000ppm	5	128± 13	75± 6	32± 3	310± 106	535± 27	2± 0	227± 31
2000ppm	5	125± 5	73± 3	30± 2	332± 146	580± 30	2± 0	268± 85
4000ppm	5	133± 9	72± 4	32± 4	339± 107	590± 38	1± 0	233± 26
8000ppm	5	142± 9	77± 5	41± 3**	463± 224	632± 56**	2± 0	253± 67

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (3W)

Group Name	NO. of Animals	UREA NITOROGEN mg/dℓ	CREATININE mg/dℓ	SODIUM mEq/ℓ	POTASSIUM mEq/ℓ	CHLORIDE mEq/ℓ	CALCIUM mg/dℓ	INORGANIC PHOSPHORUS mg/dℓ
Control	5	16.5± 1.6	0.5± 0.0	139± 2	3.7± 0.3	103± 2	9.4± 0.3	6.6± 1.2
500ppm	5	16.1± 1.0	0.5± 0.0	141± 1	3.5± 0.1	104± 2	9.7± 0.2	6.6± 0.8
1000ppm	5	16.6± 2.1	0.5± 0.0	139± 1	3.6± 0.2	103± 1	9.5± 0.2	6.6± 1.1
2000ppm	5	16.0± 2.1	0.4± 0.1	140± 0	3.5± 0.1	103± 1	9.8± 0.3	6.6± 1.1
4000ppm	5	16.4± 1.0	0.4± 0.1	140± 2	3.7± 0.4	103± 1	9.8± 0.2	7.1± 1.3
8000ppm	5	11.9± 1.0**	0.5± 0.1	137± 1	4.0± 0.3	100± 1**	9.8± 0.2	7.0± 0.9

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX H 1

GROSS FINDINGS : SUMMARY,
RAT : MALE :

(2-WEEK STUDY)

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (3W)

Organ	Findings	Group Name / NO. of Animals	Control 5 (%)	500ppm 5 (%)	1000ppm 5 (%)	2000ppm 5 (%)
liver	herniation		0 (0)	0 (0)	1 (20)	0 (0)
eye	turbid		0 (0)	0 (0)	0 (0)	0 (0)

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (3W)

Organ	Findings	Group Name / NO. of Animals	4000ppm 5 (%)	8000ppm 5 (%)
liver	herniation		1 (20)	0 (0)
eye	turbid		0 (0)	3 (60)

APPENDIX H 2

GROSS FINDINGS : SUMMARY,
RAT : FEMALE :

(2-WEEK STUDY)

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (3W)

Organ	Findings	Group Name / NO. of Animals	Control 5 (%)	500ppm 5 (%)	1000ppm 5 (%)	2000ppm 5 (%)
liver	herniation		1 (20)	0 (0)	2 (40)	1 (20)
eye	turbid		0 (0)	0 (0)	0 (0)	0 (0)

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (3W)

Organ	Findings	Group Name	4000ppm	8000ppm
		NO. of Animals	5 (%)	5 (%)
liver	herniation		0 (0)	1 (20)
eye	turbid		0 (0)	4 (80)

APPENDIX I 1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : MALE

(2-WEEK STUDY)

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (3W)

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	5	137± 3	0.296± 0.029	0.038± 0.002	2.060± 0.203	0.577± 0.013	0.687± 0.022
500ppm	5	133± 7	0.274± 0.029	0.039± 0.005	2.213± 0.141	0.575± 0.035	0.671± 0.042
1000ppm	5	137± 4	0.261± 0.014	0.037± 0.002	2.252± 0.118	0.604± 0.046	0.666± 0.024
2000ppm	5	143± 8	0.280± 0.035	0.038± 0.004	2.198± 0.214	0.593± 0.020	0.707± 0.053
4000ppm	5	150± 8*	0.284± 0.029	0.039± 0.002	2.378± 0.163	0.641± 0.036*	0.745± 0.057
8000ppm	5	123± 6*	0.155± 0.018**	0.046± 0.004**	2.109± 0.159	0.596± 0.030	0.656± 0.039

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (3W)

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	5	1.145± 0.034	0.325± 0.015	4.154± 0.157	1.681± 0.024
500ppm	5	1.131± 0.057	0.313± 0.015	4.008± 0.223	1.651± 0.027
1000ppm	5	1.150± 0.050	0.320± 0.017	4.180± 0.238	1.638± 0.025
2000ppm	5	1.198± 0.058	0.337± 0.021	4.398± 0.230	1.673± 0.038
4000ppm	5	1.336± 0.082**	0.348± 0.025	4.998± 0.357**	1.692± 0.031
8000ppm	5	1.220± 0.090	0.243± 0.013**	4.854± 0.270**	1.588± 0.037**

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX I 2

ORGAN WEIGHT, ABSOLUTE : SUMMARY,
RAT : FEMALE

(2-WEEK STUDY)

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (3W)

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	5	96± 3	0.227± 0.014	0.038± 0.003	0.053± 0.016	0.431± 0.017	0.533± 0.031
500ppm	5	99± 6	0.242± 0.020	0.042± 0.007	0.072± 0.021	0.442± 0.029	0.539± 0.032
1000ppm	5	97± 3	0.240± 0.017	0.041± 0.002	0.062± 0.014	0.454± 0.026	0.532± 0.015
2000ppm	5	99± 5	0.259± 0.043	0.041± 0.002	0.075± 0.008	0.456± 0.026	0.559± 0.041
4000ppm	5	102± 8	0.230± 0.049	0.043± 0.006	0.073± 0.011	0.491± 0.072	0.564± 0.043
8000ppm	5	92± 5	0.136± 0.011	0.052± 0.004**	0.067± 0.014	0.492± 0.031	0.533± 0.022

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (3W)

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	5	0.848± 0.026	0.234± 0.019	2.908± 0.140	1.532± 0.031
500ppm	5	0.851± 0.072	0.233± 0.025	2.993± 0.244	1.553± 0.026
1000ppm	5	0.883± 0.034	0.241± 0.010	2.997± 0.140	1.542± 0.026
2000ppm	5	0.879± 0.037	0.241± 0.027	3.202± 0.251	1.513± 0.059
4000ppm	5	0.948± 0.068*	0.243± 0.026	3.407± 0.271*	1.524± 0.019
8000ppm	5	0.945± 0.060*	0.180± 0.016**	3.727± 0.324**	1.490± 0.028

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX J 1

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : MALE

(2-WEEK STUDY)

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (3W)

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	5	137± 3	0.217± 0.022	0.027± 0.002	1.505± 0.135	0.422± 0.014	0.502± 0.013
500ppm	5	133± 7	0.206± 0.022	0.030± 0.003	1.666± 0.043	0.432± 0.010	0.505± 0.023
1000ppm	5	137± 4	0.190± 0.007	0.027± 0.002	1.640± 0.088	0.439± 0.024	0.484± 0.009
2000ppm	5	143± 8	0.196± 0.022	0.026± 0.002	1.533± 0.130	0.414± 0.012	0.493± 0.018
4000ppm	5	150± 8*	0.190± 0.014	0.026± 0.002	1.587± 0.059	0.428± 0.010	0.497± 0.015
8000ppm	5	123± 6*	0.126± 0.013**	0.037± 0.002**	1.709± 0.094*	0.483± 0.017**	0.531± 0.015*

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (3W)

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	5	0.837± 0.012	0.238± 0.010	3.036± 0.082	1.229± 0.022
500ppm	5	0.852± 0.022	0.236± 0.009	3.018± 0.071	1.246± 0.077
1000ppm	5	0.838± 0.030	0.233± 0.011	3.041± 0.087	1.193± 0.030
2000ppm	5	0.836± 0.029	0.235± 0.007	3.068± 0.023	1.170± 0.072
4000ppm	5	0.891± 0.010**	0.233± 0.017	3.335± 0.057**	1.132± 0.059
8000ppm	5	0.988± 0.036**	0.197± 0.006**	3.933± 0.051**	1.289± 0.064

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX J 2

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : FEMALE

(2-WEEK STUDY)

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (3W)

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	5	96± 3	0.236± 0.016	0.039± 0.003	0.056± 0.016	0.448± 0.027	0.553± 0.027
500ppm	5	99± 6	0.244± 0.008	0.042± 0.005	0.073± 0.018	0.448± 0.012	0.546± 0.020
1000ppm	5	97± 3	0.246± 0.019	0.042± 0.003	0.064± 0.015	0.466± 0.013	0.547± 0.022
2000ppm	5	99± 5	0.261± 0.038	0.042± 0.003	0.076± 0.009	0.460± 0.028	0.564± 0.022
4000ppm	5	102± 8	0.223± 0.033	0.042± 0.005	0.072± 0.011	0.478± 0.038	0.551± 0.025
8000ppm	5	92± 5	0.148± 0.015**	0.056± 0.003**	0.072± 0.012	0.533± 0.013**	0.578± 0.013

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0551
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (3W)

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	5	0.880± 0.018	0.243± 0.015	3.016± 0.090	1.591± 0.067
500ppm	5	0.860± 0.027	0.235± 0.013	3.027± 0.077	1.575± 0.072
1000ppm	5	0.907± 0.037	0.247± 0.007	3.078± 0.114	1.584± 0.043
2000ppm	5	0.886± 0.022	0.242± 0.018	3.227± 0.168	1.529± 0.091
4000ppm	5	0.926± 0.024*	0.237± 0.008	3.330± 0.160**	1.494± 0.095
8000ppm	5	1.025± 0.017**	0.195± 0.010**	4.038± 0.185**	1.619± 0.075

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX K

METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-WEEK INHALATION STUDY OF ISOPROPYL ACETATE

METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-WEEK INHALATION STUDY OF ISOPROPYL ACETATE

Item	Method	Unit	Decimal place
Hematology			
Red blood cell (RBC)	Light scattering method [1]	$\times 10^6/\mu L$	2
Hemoglobin (Hgb)	Cyanmethemoglobin method [1]	g/dL	1
Hematocrit (Hct)	Calculated as RBC×MCV/10 [1]	%	1
Mean corpuscular volume (MCV)	Light scattering method [1]	fL	1
Mean corpuscular hemoglobin (MCH)	Calculated as Hgb/RBC×10 [1]	pg	1
Mean corpuscular hemoglobin concentration (MCHC)	Calculated as Hgb/Hct×100 [1]	g/dL	1
Platelet	Light scattering method [1]	$\times 10^3/\mu L$	0
Reticulocyte	Light scattering method [1]	%	1
Prothrombin time	Quick one stage method [2]	sec	1
Activated partial thromboplastin time (APTT)	Ellagic acid activaterd method [2]	sec	1
White blood cell (WBC)	Light scattering method [1]	$\times 10^3/\mu L$	2
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
Aspartate aminotransferase (AST)	JSCC method [3]	IU/L	0
Alanine aminotransferase (ALT)	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)	JSCC method [3]	IU/L	0
Creatine kinase (CK)	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 coagulometer (Sysmex CA-5000 : Sysmex Corporation)

3) Automatic analyzer (Hitachi 7080 : Hitachi,Ltd.)