2,4-ペンタンジオンのラットを用いた
吸入による 2 週間毒性試験報告書

試験番号：0582

APPENDICES

APPENDICES

APPENDICES (CONTINUED)

APPENDIX A 1

IDENTITY OF 2,4-PENTANEDIONE

IN THE 2-WEEK INHALATION STUDY

IDENTITY OF 2,4-PENTANEDIONE IN THE 2-WEEK INHALATION STUDY

Test Substance : 2,4-Pentanedione (Wako Pure Chemical Industries, Ltd.)

Lot No. : CHE5187

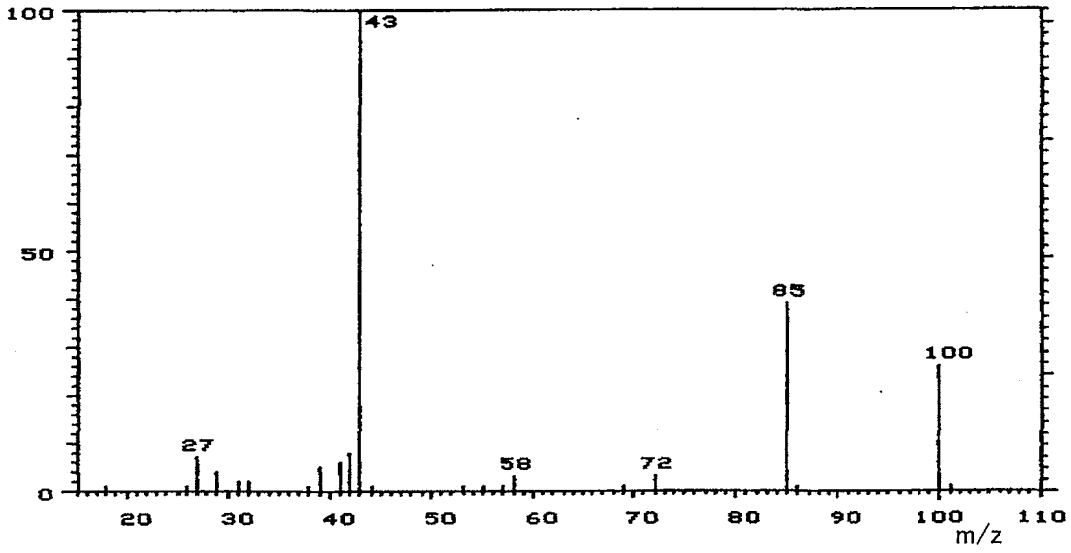
1. Spectral Data

Mass Spectrometry

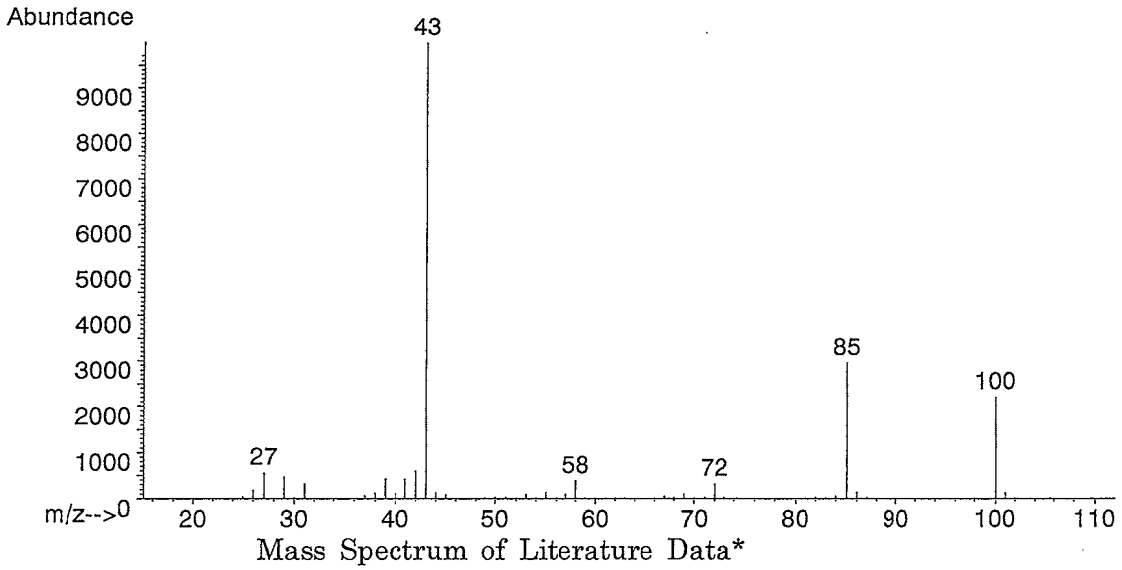
Instrument : Hitachi M-80B Mass Spectrometer

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.

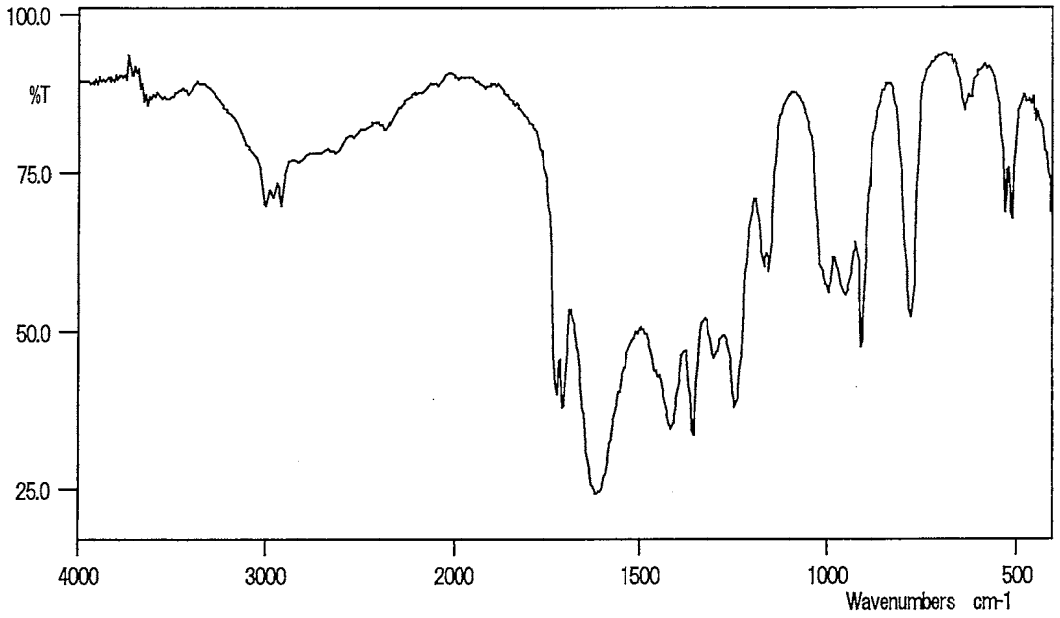
(*McLafferty FW, ed. 1994. Wiley Registry of Mass Spectral Data. 6th ed. New York, NY:John Wiley and Sons.)

Infrared Spectrometry

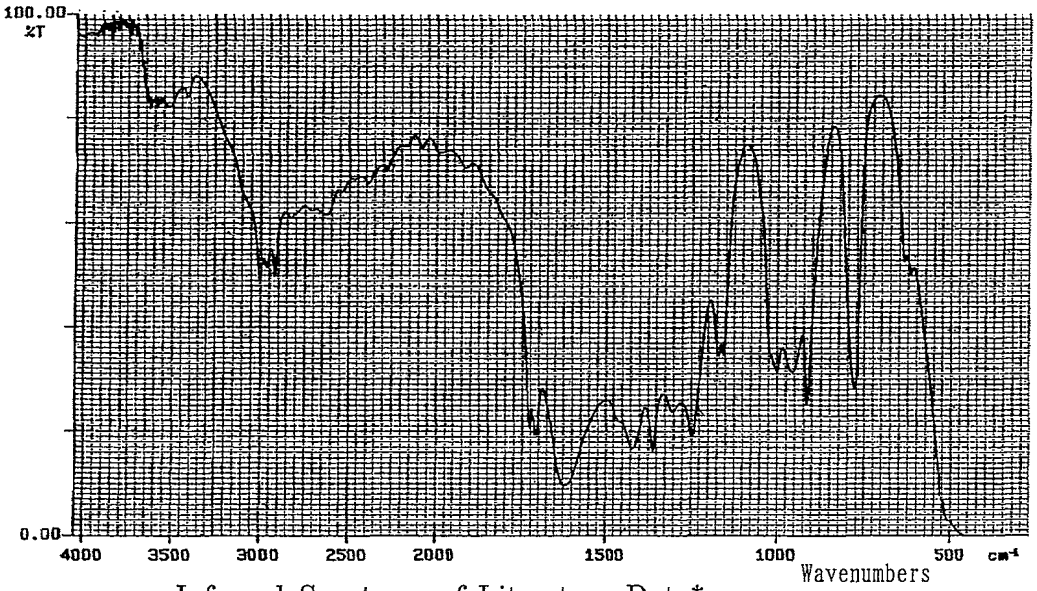
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

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. Conclusion: The test substance was identified as 2,4-pentanedione by mass spectrum and infrared spectrum.

APPENDIX A 2

STABILITY OF 2,4-PENTANEDIONE

IN THE 2-WEEK INHALATION STUDY

STABILITY OF 2,4-PENTANEDIONE IN THE 2-WEEK INHALATION STUDY

Test Substance : 2,4-Pentanedione (Wako Pure Chemical Industries, Ltd.)

Lot No. : CHE5187

1. Sample : This lot was used from 2005.3.1 to 2005.3.14. Test substance was stored in a dark place at room temperature.

2. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : INNOWAX (0.53 mmϕ × 60 m)

Column Temperature: 150° C

Flow Rate : 3 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μL

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
2005.02.28	1	6.133	100
2005.03.23	1	6.146	100

Result: Gas chromatography indicated one major peak (peak No.1) analyzed on 2005.2.28 and one major peak (peak No.1) analyzed on 2005.3.23. No new trace impurity peak in the test substance analyzed on 2005.3.23 was detected.

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

APPENDIX B

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 2-WEEK INHALATION STUDY OF 2,4-PENTANEDIONE

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 2-WEEK INHALATION STUDY OF 2,4-PENTANEDIONE

Group Name	Temperature (℃) Mean ± S.D.	Humidity (%) Mean ± S.D.	Ventilation Rate (L/min) Mean ± S.D.	Air Change (time/h) Mean
Control	22.1 ± 0.2	58.7 ± 0.5	212.3 ± 0.9	12.0
50 ppm	21.9 ± 0.2	60.6 ± 1.1	213.0 ± 0.7	12.0
100 ppm	21.9 ± 0.2	59.8 ± 1.2	213.3 ± 0.7	12.1
200 ppm	21.8 ± 0.3	58.9 ± 1.4	212.8 ± 0.7	12.0
400 ppm	22.0 ± 0.2	56.9 ± 1.8	212.4 ± 1.0	12.0
800 ppm	21.7 ± 0.2	58.2 ± 1.6	213.1 ± 0.5	12.1

APPENDIX C 1

CLINICAL OBSERVATION : MALE

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[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 1	1-4 1	1-7 1	2-3 1	2-7 1
DEATH	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	0	0	4	5	5	5	-	-
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	5	0	0	0	-	-	-	-
PRONE	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	4	0	0	0	-	-	-	-
LATERAL	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	0	0	1	0	-	-	-	-
STEP BACK	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	1	0	0	0	-	-	-	-
TOUCH-RESPONSE. DISAPPEAR	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	0	0	1	0	-	-	-	-

Clinical sign	Group Name	Administration Week-day 1-1 2	1-2 1	1-2 2	1-3 1	1-4 1	1-7 1	2-3 1	2-7 1
JUMPING	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	5	0	0	0	-	-	-	-
LACRIMATION	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	5	0	1	0	-	-	-	-
NOSE HEMORRHAGIC DISCHA	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	1	0	0	0	-	-	-	-
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	3	0	0	0	-	-	-	-
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	2	0	0	0	-	-	-	-
BRADYPNEA	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	3	0	1	0	-	-	-	-

Clinical sign	Group Name	Administration Week-day 1-1 2	1-2 1	1-2 2	1-3 1	1-4 1	1-7 1	2-3 1	2-7 1
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	0	0	1	0	-	-	-	-
SALIVATION	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	4	0	0	0	-	-	-	-

APPENDIX C 2

CLINICAL OBSERVATION : FEMALE

Clinical sign	Group Name	Administration Week-day 1-1 2	1-2 1	1-2 2	1-3 1	1-4 1	1-7 1	2-3 1	2-7 1
DEATH	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	0	0	5	5	5	5	-	-
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	5	0	0	-	-	-	-	-
PRONE	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	4	0	0	-	-	-	-	-
LATERAL	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	1	0	0	-	-	-	-	-
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	2	0	0	-	-	-	-	-
STEP BACK	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	1	0	0	-	-	-	-	-

Clinical sign	Group Name	Administration Week-day 1-1 2	1-2 1	1-2 2	1-3 1	1-4 1	1-7 1	2-3 1	2-7 1
JUMPING	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	5	0	0	-	-	-	-	-
LACRIMATION	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	4	0	0	-	-	-	-	-
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	2	0	0	-	-	-	-	-
BRADYPNEA	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	3	0	0	-	-	-	-	-
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	1	0	0	-	-	-	-	-
SALIVATION	Control	0	0	0	0	0	0	0	0
	50ppm	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0
	800ppm	3	0	0	-	-	-	-	-

APPENDIX D 1

BODY WEIGHT CHANGES : MALE

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[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	2-3	2-7
Control	126± 5	132± 6	137± 7	148± 8	159± 9	175± 8
50ppm	127± 4	131± 4	134± 4	146± 5	156± 7	171± 8
100ppm	126± 5	132± 7	136± 7	147± 9	157± 10	174± 10
200ppm	127± 3	131± 3	134± 5	145± 4	154± 4	173± 3
400ppm	126± 5	128± 5	128± 5	141± 7	145± 7	160± 7*
800ppm	127± 3	115 ?	-	-	-	-

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

? : Significant test is not applied, because No. of data in this group is less than 3.

APPENDIX D 2

BODY WEIGHT CHANGES : FEMALE

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[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	2-3	2-7
Control	99± 2	102± 3	102± 3	108± 4	113± 4	122± 4
50ppm	99± 2	101± 4	103± 5	109± 6	112± 5	119± 6
100ppm	99± 2	101± 1	102± 2	107± 2	110± 1	117± 3
200ppm	99± 2	101± 2	103± 3	110± 5	112± 5	121± 5
400ppm	99± 3	98± 3	97± 3	104± 3	105± 3**	113± 4*
800ppm	99± 3	-	-	-	-	-

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

APPENDIX E 1

FOOD CONSUMPTION CHANGES : MALE

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
UNIT : g
REPORT TYPE : A1 2
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day(effective) 1-7(6)	2-7(7)
Control	15.2± 1.1	15.0± 1.2
50ppm	15.3± 1.0	15.6± 1.1
100ppm	15.5± 0.7	15.4± 0.6
200ppm	14.9± 0.6	15.3± 0.3
400ppm	13.7± 0.9*	13.3± 0.7*
800ppm	-	-

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

APPENDIX E 2

FOOD CONSUMPTION CHANGES : FEMALE

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
UNIT : g
REPORT TYPE : A1 2
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration 1-7(6)	week-day(effective) 2-7(7)
Control	11.5± 0.5	11.7± 1.2
50ppm	12.1± 0.9	11.5± 0.8
100ppm	11.6± 0.1	11.3± 0.3
200ppm	11.8± 1.0	11.5± 0.8
400ppm	10.6± 0.4*	9.9± 0.4**
800ppm	-	-

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

APPENDIX F 1

HEMATOLOGY : MALE

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[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 fℓ	MCH pg	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
Control	5	8.82± 0.14	16.0± 0.3	47.6± 0.5	54.0± 0.5	18.1± 0.2	33.5± 0.4	948± 33
50ppm	5	8.91± 0.43	16.2± 0.7	47.9± 2.0	53.7± 0.4	18.2± 0.2	33.8± 0.3	938± 52
100ppm	5	8.82± 0.23	16.0± 0.5	47.3± 1.1	53.6± 0.3	18.1± 0.1	33.7± 0.2	965± 38
200ppm	5	8.85± 0.12	16.0± 0.1	47.0± 0.6	53.2± 0.3*	18.1± 0.1	34.0± 0.1	952± 26
400ppm	5	8.84± 0.17	15.9± 0.2	46.1± 0.8	52.2± 0.6**	18.0± 0.3	34.6± 0.5**	896± 21
800ppm	0	-	-	-	-	-	-	-

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

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (3W)

Group Name	NO. of Animals	RETICULOCYTE %
Control	5	2.9± 0.3
50ppm	5	2.8± 0.3
100ppm	5	2.8± 0.4
200ppm	5	2.9± 0.3
400ppm	5	3.1± 0.5
800ppm	0	-

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

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[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	5.47± 1.24	
50ppm	5	4.24± 1.26	
100ppm	5	4.20± 0.60	
200ppm	5	4.82± 1.13	
400ppm	5	5.07± 1.31	
800ppm	0	-	

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

APPENDIX F 2

HEMATOLOGY : FEMALE

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[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/μl	HEMOGLOBIN g/dl	HEMATOCRIT %	MCV f l	MCH p g	MCHC g/dl	PLATELET 10^3/μl
Control	5	9.03± 0.05	16.7± 0.2	48.3± 0.3	53.4± 0.1	18.4± 0.2	34.5± 0.4	864± 48
50ppm	5	8.99± 0.22	16.5± 0.3	48.2± 1.0	53.6± 0.3	18.3± 0.2	34.3± 0.3	791± 33
100ppm	5	9.04± 0.19	16.7± 0.4	48.2± 0.9	53.3± 0.3	18.5± 0.1	34.6± 0.1	836± 45
200ppm	5	9.11± 0.23	16.7± 0.3	47.9± 1.1	52.6± 0.3**	18.4± 0.3	34.9± 0.3	885± 62
400ppm	5	8.87± 0.13	16.1± 0.3*	46.1± 0.7**	52.0± 0.2**	18.1± 0.2	34.9± 0.3	804± 42
800ppm	0	-	-	-	-	-	-	-

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

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (3W)

Group Name	NO. of Animals	RETICULOCYTE %
Control	5	1.5± 0.3
50ppm	5	1.6± 0.2
100ppm	5	1.6± 0.1
200ppm	5	1.7± 0.2
400ppm	5	1.9± 0.1
800ppm	0	-

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

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (3W)

Group Name	NO. of Animals	WBC $10^3/\mu\ell$	Differential WBC (%)
Control	5	3.28± 0.84	
50ppm	5	3.23± 0.58	
100ppm	5	3.59± 0.82	
200ppm	5	3.22± 0.44	
400ppm	5	4.76± 0.72*	
800ppm	0	-	

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

APPENDIX G 1

BIOCHEMISTRY : MALE

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[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		GLUCOSE mg／dℓ		T-CHOLESTEROL mg／dℓ		AST IU／ℓ		ALT IU／ℓ	
Control	5	5.8±	0.1	3.4±	0.1	153±	16	48±	5	67±	3	34±	2
50ppm	5	5.9±	0.1	3.5±	0.1	150±	11	49±	4	67±	1	35±	1
100ppm	5	5.7±	0.1	3.4±	0.1	161±	13	48±	3	68±	2	34±	2
200ppm	5	5.9±	0.2	3.5±	0.1	158±	11	52±	6	66±	3	36±	3
400ppm	5	5.7±	0.1	3.5±	0.1	177±	14*	51±	2	64±	5	31±	2
800ppm	0	-		-		-		-		-		-	

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

APPENDIX G 2

BIOCHEMISTRY : FEMALE

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[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	GLUCOSE mg／dℓ	T-CHOLESTEROL mg／dℓ	AST IU／ℓ	ALT IU／ℓ
Control	5	5.7± 0.1	3.4± 0.0	130± 15	68± 2	71± 4	32± 2
50ppm	5	5.7± 0.0	3.4± 0.0	142± 20	62± 3	72± 2	31± 2
100ppm	5	5.6± 0.1	3.4± 0.0	135± 11	64± 4	69± 3	32± 1
200ppm	5	5.7± 0.0	3.5± 0.1	152± 9*	66± 3	66± 3	32± 4
400ppm	5	5.5± 0.1*	3.3± 0.1	159± 8**	75± 5*	61± 3**	30± 1
800ppm	0	-	-	-	-	-	-

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

APPENDIX H 1

GROSS FINDINGS : MALE

DEAD AND MORIBUND ANIMALS

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 3W)

Organ	Findings	Group Name / NO. of Animals	Control 0	(%)	50ppm 0	(%)	100ppm 0	(%)	200ppm 0	(%)
eye	turbid		-	(-)	-	(-)	-	(-)	-	(-)

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 3W)

Organ	Findings	Group Name / NO. of Animals	400ppm 0 (%)	800ppm 5 (%)
eye	turbid		- (-)	3 (60)

APPENDIX H 2

GROSS FINDINGS : MALE

SACRIFICED ANIMALS

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (3W)

Organ	Findings	Group Name / NO. of Animals	Control 5 (%)	50ppm 5 (%)	100ppm 5 (%)	200ppm 5 (%)
liver	herniation		0 (0)	0 (0)	0 (0)	0 (0)

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (3W)

Organ	Findings	Group Name	400ppm	800ppm
		NO. of Animals	5 (%)	0 (%)
liver	herniation		1 (20)	- (-)

APPENDIX H 3

GROSS FINDINGS : FEMALE

DEAD AND MORIBUND ANIMALS

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 3W)

Organ	Findings	Group Name / NO. of Animals	Control 0 (%)	50ppm 0 (%)	100ppm 0 (%)	200ppm 0 (%)
eye	turbid		- (-)	- (-)	- (-)	- (-)
	white		- (-)	- (-)	- (-)	- (-)

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 3W)

Organ	Findings	Group Name / NO. of Animals	400ppm 0 (%)	800ppm 5 (%)
eye	turbid		- (-)	1 (20)
	white		- (-)	3 (60)

APPENDIX H 4

GROSS FINDINGS : FEMALE

SACRIFICED ANIMALS

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (3W)

Organ	Findings	Group Name / NO. of Animals	Control 5 (%)	50ppm 5 (%)	100ppm 5 (%)	200ppm 5 (%)
liver	herniation		0 (0)	1 (20)	0 (0)	1 (20)

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (3W)

Organ	Findings	Group Name	400ppm	800ppm
		NO. of Animals	5 (%)	0 (%)
liver	herniation		2 (40)	- (-)

APPENDIX I 1

ORGAN WEIGHT, ABSOLUTE : MALE

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[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	157± 9	0.280± 0.025	0.046± 0.006	2.532± 0.135	0.619± 0.014	0.704± 0.043
50ppm	5	155± 8	0.243± 0.025	0.044± 0.003	2.515± 0.083	0.610± 0.044	0.675± 0.023
100ppm	5	155± 9	0.243± 0.032	0.045± 0.004	2.496± 0.081	0.612± 0.028	0.680± 0.031
200ppm	5	153± 3	0.221± 0.012**	0.044± 0.002	2.541± 0.048	0.625± 0.027	0.673± 0.016
400ppm	5	145± 6	0.211± 0.012**	0.045± 0.003	2.487± 0.163	0.609± 0.023	0.655± 0.036
800ppm	0	-	-	-	-	-	-

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

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[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	1.278± 0.074	0.372± 0.039	4.697± 0.323	1.666± 0.033
50ppm	5	1.262± 0.078	0.359± 0.027	4.602± 0.267	1.670± 0.025
100ppm	5	1.258± 0.054	0.360± 0.024	4.630± 0.251	1.660± 0.038
200ppm	5	1.282± 0.047	0.361± 0.020	4.798± 0.092	1.683± 0.027
400ppm	5	1.272± 0.016	0.348± 0.026	4.795± 0.348	1.650± 0.037
800ppm	0	-	-	-	-

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

APPENDIX I 2

ORGAN WEIGHT, ABSOLUTE : FEMALE

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[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	108± 4	0.220± 0.019	0.047± 0.003	0.078± 0.001	0.463± 0.015	0.544± 0.023
50ppm	5	106± 4	0.199± 0.014	0.050± 0.003	0.077± 0.006	0.471± 0.029	0.545± 0.022
100ppm	5	105± 3	0.211± 0.015	0.049± 0.004	0.078± 0.007	0.468± 0.010	0.534± 0.026
200ppm	5	107± 4	0.212± 0.033	0.047± 0.004	0.077± 0.005	0.471± 0.009	0.545± 0.022
400ppm	5	101± 4	0.183± 0.015	0.045± 0.002	0.079± 0.007	0.473± 0.009	0.524± 0.017
800ppm	0	-	-	-	-	-	-

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

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[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	0.924± 0.017	0.271± 0.015	3.259± 0.091	1.550± 0.022
50ppm	5	0.923± 0.022	0.255± 0.017	3.347± 0.168	1.568± 0.022
100ppm	5	0.936± 0.040	0.265± 0.016	3.228± 0.151	1.570± 0.018
200ppm	5	0.944± 0.048	0.272± 0.024	3.346± 0.145	1.543± 0.038
400ppm	5	0.943± 0.024	0.249± 0.015	3.372± 0.144	1.522± 0.019
800ppm	0	-	-	-	-

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

APPENDIX J 1

ORGAN WEIGHT, RELATIVE : MALE

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[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	157± 9	0.179± 0.020	0.029± 0.004	1.615± 0.093	0.396± 0.030	0.449± 0.030
50ppm	5	155± 8	0.157± 0.011*	0.029± 0.003	1.631± 0.109	0.394± 0.010	0.437± 0.013
100ppm	5	155± 9	0.157± 0.013*	0.029± 0.002	1.615± 0.066	0.396± 0.011	0.440± 0.025
200ppm	5	153± 3	0.145± 0.006**	0.029± 0.001	1.659± 0.037	0.408± 0.017	0.440± 0.009
400ppm	5	145± 6	0.146± 0.013**	0.031± 0.002	1.715± 0.092	0.420± 0.022	0.452± 0.014
800ppm	0	-	-	-	-	-	-

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

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[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	0.814± 0.011	0.236± 0.013	2.990± 0.043	1.064± 0.052
50ppm	5	0.816± 0.027	0.233± 0.010	2.976± 0.065	1.082± 0.041
100ppm	5	0.814± 0.018	0.232± 0.010	2.993± 0.057	1.075± 0.058
200ppm	5	0.836± 0.023	0.236± 0.014	3.132± 0.063*	1.099± 0.037
400ppm	5	0.878± 0.029**	0.240± 0.011	3.304± 0.143**	1.139± 0.048
800ppm	0	-	-	-	-

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

APPENDIX J 2

ORGAN WEIGHT, RELATIVE : FEMALE

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[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	108± 4	0.203± 0.012	0.043± 0.002	0.072± 0.003	0.429± 0.015	0.504± 0.014
50ppm	5	106± 4	0.187± 0.014	0.047± 0.002	0.072± 0.004	0.443± 0.012	0.512± 0.012
100ppm	5	105± 3	0.201± 0.010	0.047± 0.004	0.074± 0.005	0.447± 0.017	0.510± 0.012
200ppm	5	107± 4	0.197± 0.024	0.044± 0.004	0.072± 0.005	0.440± 0.014	0.509± 0.024
400ppm	5	101± 4	0.181± 0.011	0.044± 0.003	0.078± 0.006	0.467± 0.013**	0.518± 0.012
800ppm	0	-	-	-	-	-	-

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

STUDY NO. : 0582
ANIMAL : RAT F344/DuCrlCrlj[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	0.857± 0.035	0.251± 0.008	3.018± 0.037	1.436± 0.051
50ppm	5	0.868± 0.023	0.240± 0.010	3.145± 0.080**	1.475± 0.051
100ppm	5	0.895± 0.032	0.253± 0.010	3.085± 0.079	1.501± 0.038
200ppm	5	0.880± 0.021	0.253± 0.014	3.121± 0.041*	1.441± 0.068
400ppm	5	0.932± 0.040**	0.246± 0.008	3.331± 0.044**	1.505± 0.058
800ppm	0	-	-	-	-

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 2,4-PENTANEDIONE

METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-WEEK INHALATION STUDY OF 2,4-PENTANEDIONE

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
White blood cell(WBC)	Light scattering method [1]	$\times 10^3/\mu L$	2
Biochemistry			
Total protein(TP)	Biuret method [2]	g/dL	1
Albumin (Alb)	BCG method [2]	g/dL	1
Glucose	GlcK·G-6-PDH method [2]	mg/dL	0
T-cholesterol	CE·COD·POD method [2]	mg/dL	0
Aspartate aminotransferase (AST)	JSCC method [2]	IU/L	0
Alanine aminotransferase (ALT)	JSCC method [2]	IU/L	0

1) Automatic blood cell analyzer (ADVIA120 : Bayer Corporation)
2) Automatic analyzer (Hitachi 7080 : Hitachi,Ltd.)