

アクリル酸メチルのマウスを用いた吸入によるがん原性試験報告書

試験番号：0832

APPENDICES

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APPENDIX 1-1

IDENTITY OF METHYL ACRYLATE IN THE INHALATION
CARCINOGENICITY STUDY

IDENTITY OF METHYL ACRYLATE IN THE INHALATION CARCINOGENICITY STUDY

Test Substance : Methyl acrylate (Wako Pure Chemical Industries, Ltd.)

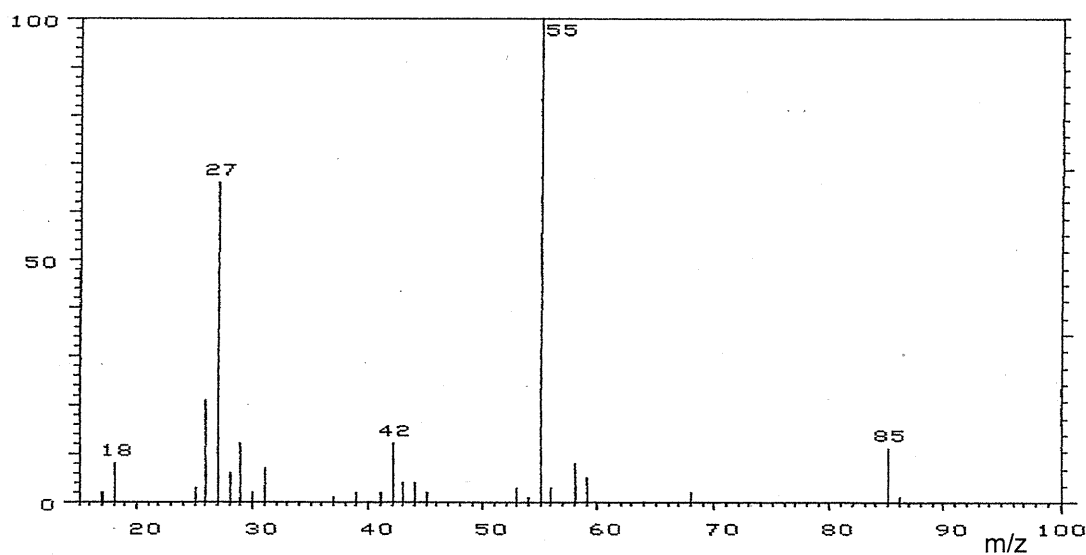
A. Lot No. : AWF1535

1. Mass Spectrometry

Instrument : Hitachi M-80B Mass Spectrometer

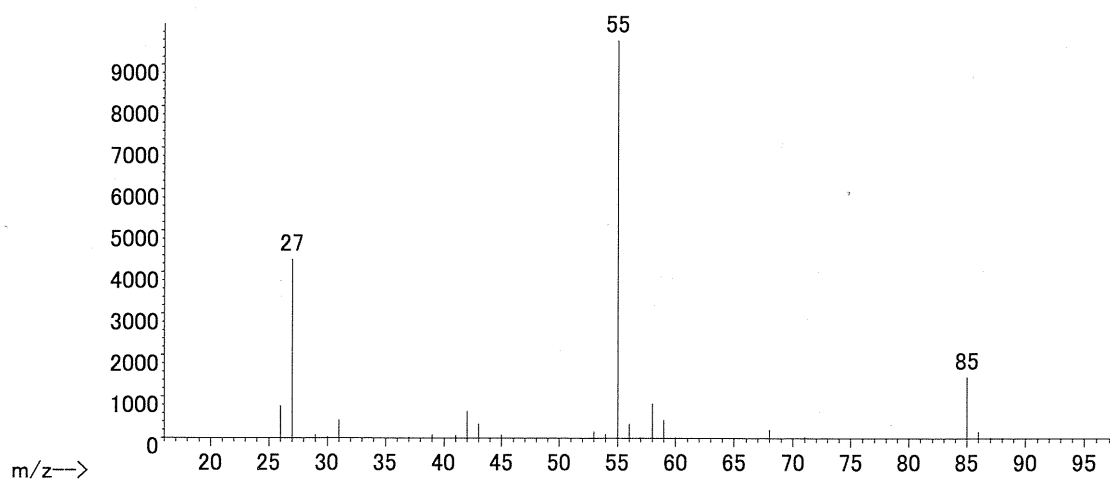
Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance

abundance



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.)

2. Conclusion: The test substance was identified as methyl acrylate by mass spectrum.

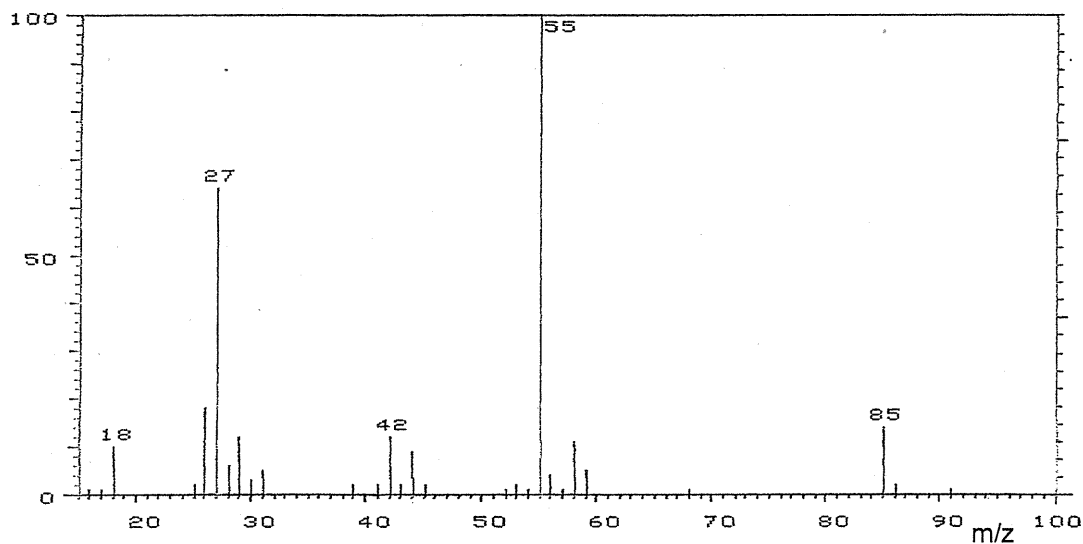
B. Lot No. : KPJ3619

1. Mass Spectrometry

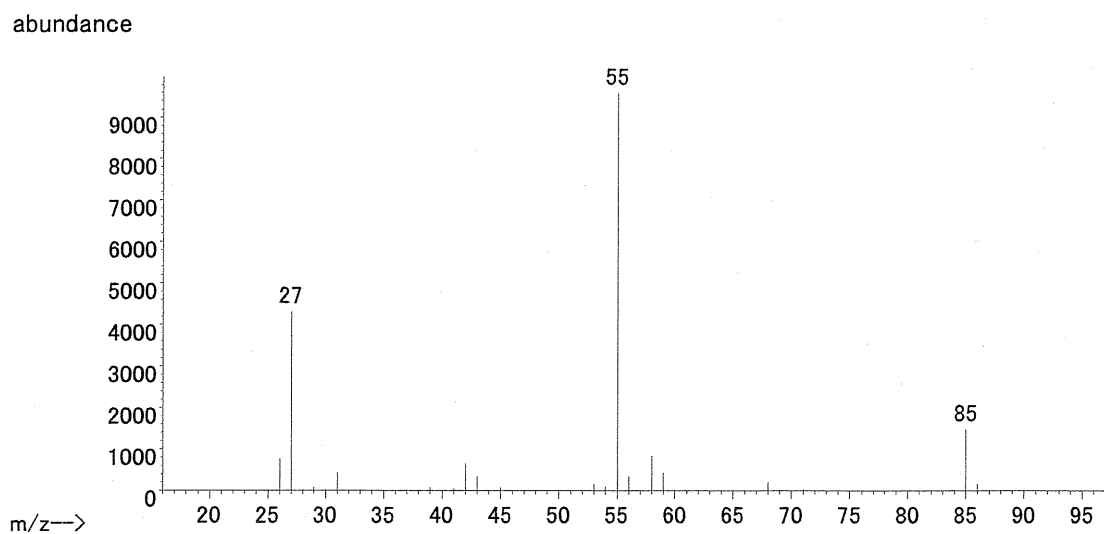
Instrument : Hitachi M-80B Mass Spectrometer

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.)

2. Conclusion: The test substance was identified as methyl acrylate by mass spectrum.

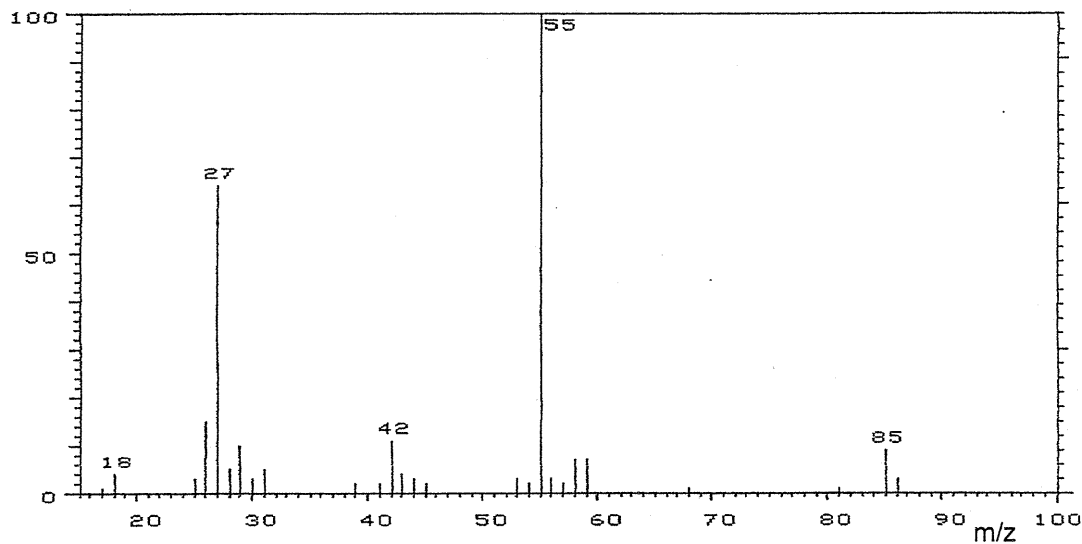
C. Lot No. : ECL0060

1. Mass Spectrometry

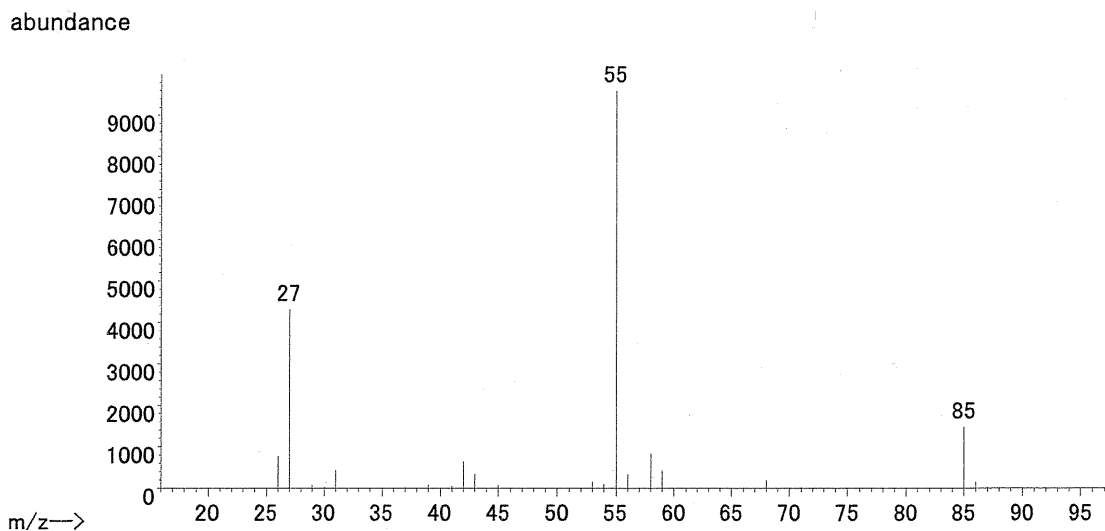
Instrument : Hitachi M-80B Mass Spectrometer

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.)

2. Conclusion: The test substance was identified as methyl acrylate by mass spectrum.

APPENDIX 1-2

STABILITY OF METHYL ACRYLATE IN THE INHALATION
CARCINOGENICITY STUDY

STABILITY OF METHYL ACRYLATE IN THE INHALATION CARCINOGENICITY STUDY

Test Substance : Methyl acrylate (Wako Pure Chemical Industries, Ltd.)

A. Lot No. : AWF1535

1. Gas Chromatography

Instrument : Agilent Technologies 5890A Gas Chromatograph

Column : INNOWAX (0.53 mm ϕ \times 60 m)

Column Temperature : 78 °C

Flow Rate : 5 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μ L

Date Analyzed	Peak No.	Retention Time (min)	Area (%)
2014.01.17	1	4.724	100
2014.11.06	1	4.757	100

Result: Gas chromatography indicated one major peak (peak No.1) analyzed on 2014.1.17 and one major peak (peak No.1) analyzed on 2014.11.6. No new trace impurity peak in the test substance analyzed on 2014.11.6 was detected.

2. Conclusion: The test substance was stable for the period that the test substance had been used for the study.

B. Lot No. : KPJ3619

1. Gas Chromatography

Instrument : Agilent Technologies 5890A Gas Chromatograph

Column : INNOWAX (0.53 mm ϕ \times 60 m)

Column Temperature : 78 °C

Flow Rate : 5 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μ L

Date Analyzed	Peak No.	Retention Time (min)	Area (%)
2014.10.31	1	4.702	100
2015.08.20	1	4.714	100

Result: Gas chromatography indicated one major peak (peak No.1) analyzed on 2014.10.31 and one major peak (peak No.1) analyzed on 2015.8.20. No new trace impurity peak in the test substance analyzed on 2015.8.20 was detected.

2. Conclusion: The test substance was stable for the period that the test substance had been used for the study.

C. Lot No. : ECL0060

1. Gas Chromatography

Instrument : Agilent Technologies 5890A Gas Chromatograph

Column : INNOWAX (0.53 mm ϕ \times 60 m)

Column Temperature : 78 °C

Flow Rate : 5 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μ L

Date Analyzed	Peak No.	Retention Time (min)	Area (%)
2015.08.18	1	4.719	100
2016.02.05	1	4.717	100

Result: Gas chromatography indicated one major peak (peak No.1) analyzed on 2015.8.18 and one major peak (peak No.1) analyzed on 2016.2.5. No new trace impurity peak in the test substance analyzed on 2016.2.5 was detected.

2. Conclusion: The test substance was stable for the period that the test substance had been used for the study.

APPENDIX 2

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE INHALATION CARCINOGENICITY STUDY OF METHYL ACRYLATE

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE
INHALATION CARCINOGENICITY STUDY OF METHYL ACRYLATE

Group Name	Temperature (°C) Mean ± S.D.	Humidity (%) Mean ± S.D.	Ventilation Rate (L/min) Mean ± S.D.	Air Change (time/h) Mean
Control	23.1 ± 0.0	52.5 ± 0.9	780.8 ± 4.4	12.0
2.5 ppm	22.9 ± 0.0	52.0 ± 1.0	779.8 ± 4.4	12.0
10 ppm	23.0 ± 0.0	52.1 ± 0.8	777.0 ± 5.4	12.0
40 ppm	23.0 ± 0.0	54.3 ± 1.0	779.0 ± 4.1	12.0

APPENDIX 3

METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE INHALATION CARCINOGENICITY STUDY OF METHYL ACRYLATE

METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY
IN THE INHALATION CARCINOGENICITY STUDY OF METHYL ACRYLATE

Item	Method	Unit	Decimal place
Hematology			
Red blood cell (RBC)	Light scattering method ¹⁾	$\times 10^6/\mu\text{L}$	2
Hemoglobin(Hgb)	Cyanmethemoglobin method ¹⁾	g/dL	1
Hematocrit(Hct)	Calculated as $\text{RBC} \times \text{MCV}/10$ ¹⁾	%	1
Mean corpuscular volume(MCV)	Light scattering method ¹⁾	fL	1
Mean corpuscular hemoglobin(MCH)	Calculated as $\text{Hgb}/\text{RBC} \times 10$ ¹⁾	pg	1
Mean corpuscular hemoglobin concentration (MCHC)	Calculated as $\text{Hgb}/\text{Hct} \times 100$ ¹⁾	g/dL	1
Platelet	Light scattering method ¹⁾	$\times 10^3/\mu\text{L}$	0
Reticulocyte	Light scattering method ¹⁾	%	1
White blood cell(WBC)	Light scattering method ¹⁾	$\times 10^3/\mu\text{L}$	2
Differential WBC	Light scattering method ¹⁾	%	0
Biochemistry			
Total protein(TP)	Biuret method ²⁾	g/dL	1
Albumin (Alb)	BCG method ²⁾	g/dL	1
A/G ratio	Calculated as $\text{Alb}/(\text{TP} - \text{Alb})$ ²⁾	—	1
T-bilirubin	BOD method ²⁾	mg/dL	2
Glucose	GlcK·G-6-PDH method ²⁾	mg/dL	0
T-cholesterol	CE·COD·POD method ²⁾	mg/dL	0
Triglyceride	MGLP·GK·GPO·POD method ²⁾	mg/dL	0
Phospholipid	PLD·ChOD·POD method ²⁾	mg/dL	0
Aspartate aminotransferase (AST)	JSCC method ²⁾	U/L	0
Alanine aminotransferase (ALT)	JSCC method ²⁾	U/L	0
Lactate dehydrogenase (LDH)	JSCC method ²⁾	U/L	0
Alkaline phosphatase (ALP)	JSCC method ²⁾	U/L	0
γ -Glutamyl transpeptidase (γ -GTP)	JSCC method ²⁾	U/L	1
Creatine kinase (CK)	JSCC method ²⁾	U/L	0
Urea nitrogen	Urease·GLDH method ²⁾	mg/dL	1
Sodium	Ion selective electrode method ²⁾	mEq/L	0
Potassium	Ion selective electrode method ²⁾	mEq/L	1
Chloride	Ion selective electrode method ²⁾	mEq/L	0
Calcium	OCPC method ²⁾	mg/dL	1
Inorganic phosphorus	PNP·XOD·POD method ²⁾	mg/dL	1

1) Automatic blood cell analyzer (ADVIA120 : Siemens Healthcare Diagnostics Inc.)

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