

メチルアミン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：0732

APPENDICES

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APPENDIX 1-1

IDENTITY OF METHYLAMINE
IN THE 2-YEAR INHALATION STUDY

IDENTITY OF METHYLAMINE IN THE 2-YEAR INHALATION STUDY

Test Substance : Methylamine (MITSUBISHI GAS CHEMICAL COMPANY, INC.)

A: Lot No. : M70124

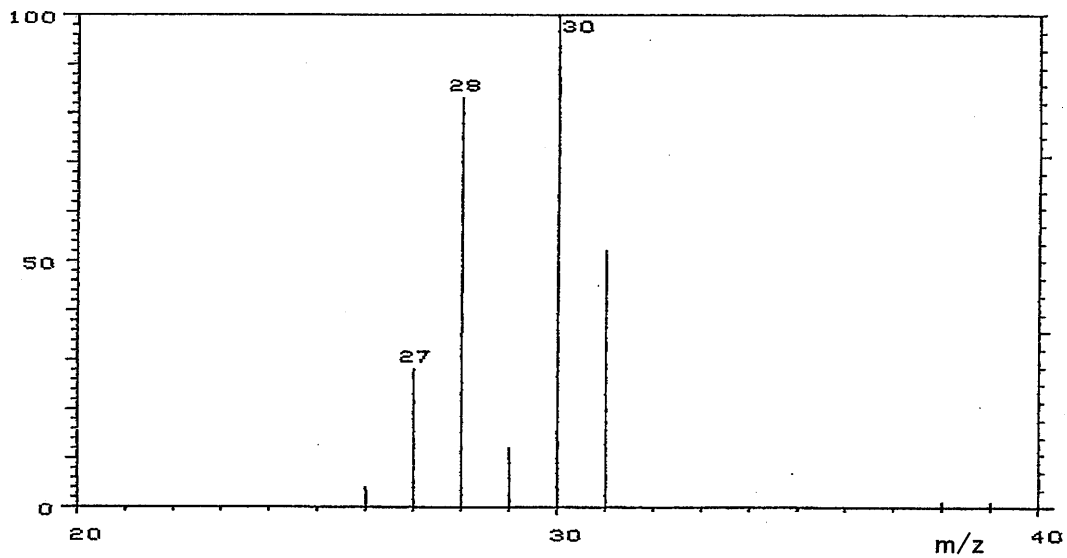
1. Spectral Data

Mass Spectrometry

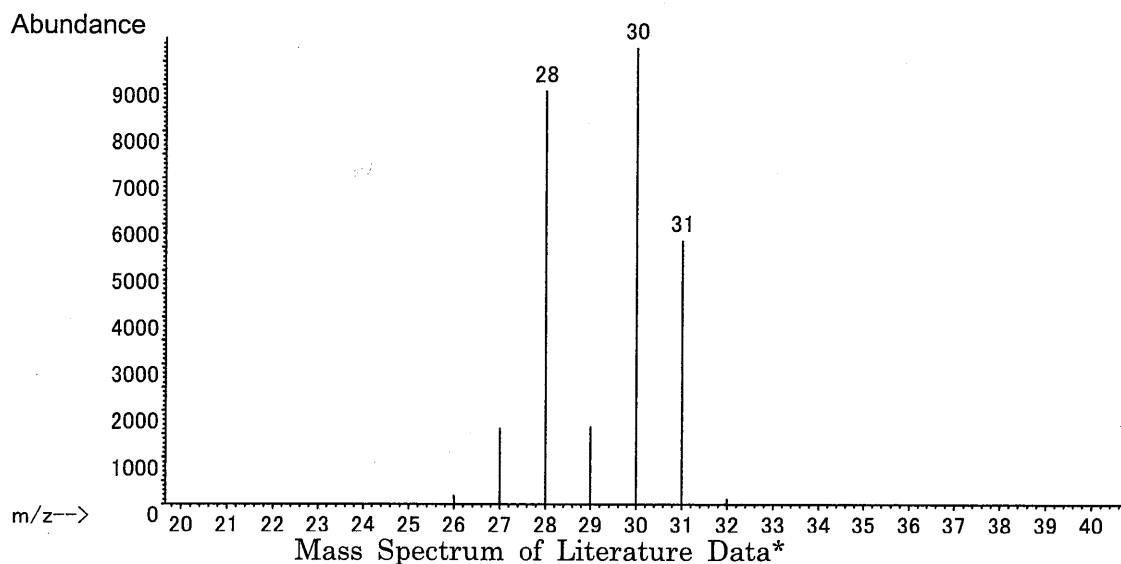
Instrument : Hitachi M-80B Mass Spectrometer

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.)

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

B: Lot No. : M81120

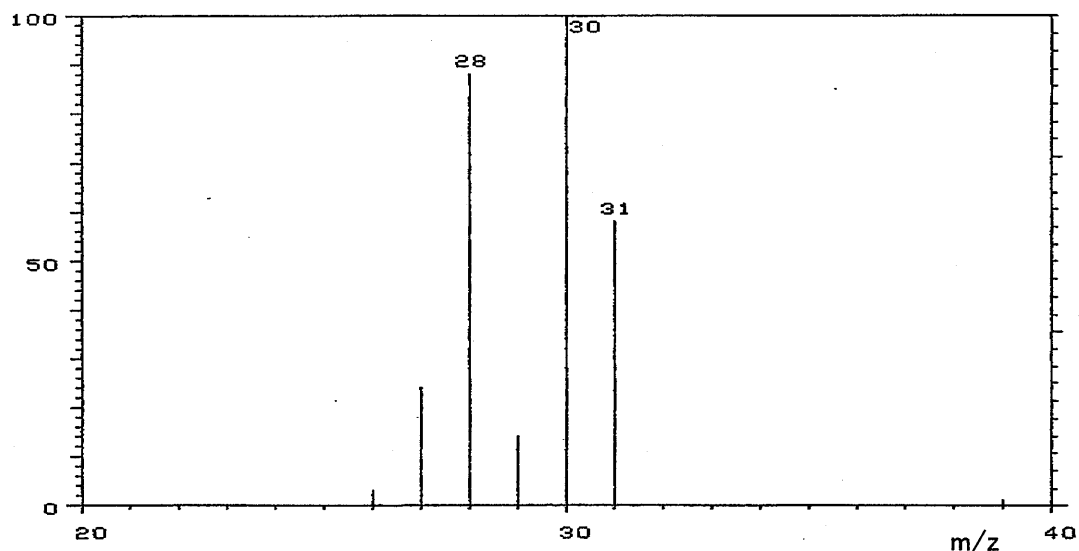
1. Spectral Data

Mass Spectrometry

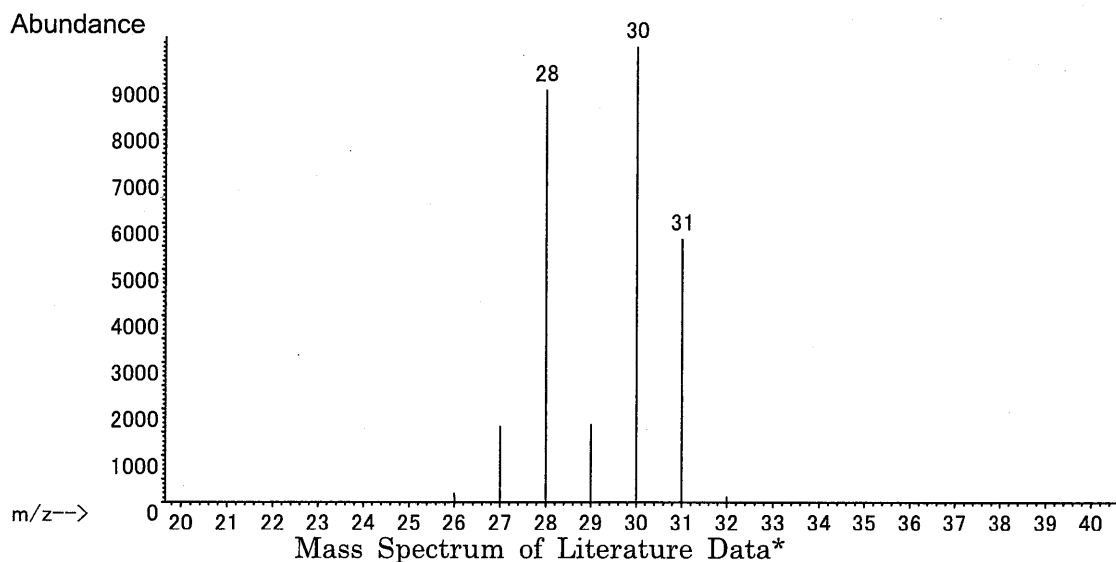
Instrument : Hitachi M-80B Mass Spectrometer

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.)

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

APPENDIX 1-2

STABILITY OF METHYLAMINE
IN THE 2-YEAR INHALATION STUDY

STABILITY OF METHYLAMINE IN THE 2-YEAR INHALATION STUDY

Test Substance : Methylamine (MITSUBISHI GAS CHEMICAL COMPANY, INC.)

A: Lot No. : M70124

1. Gas Chromatography

Instrument : Agilent Technologies 5890A Gas Chromatograph

Column : 4%Carbowax 20M + 0.8%KOH (2 mm ϕ \times 2 m)

Column Temperature: 60° C

Flow Rate : 10 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 250 μ L

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
2009.01.29	1	0.965	100
2009.11.24	1	0.938	100

Result: Gas chromatography indicated one major peak (peak No.1) analyzed on 2009.1.29 and one major peak (peak No.1) analyzed on 2009.11.24. No new trace impurity peak in the test substance analyzed on 2009.11.24 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. : M81120

1. Gas Chromatography

Instrument : Agilent Technologies 5890A Gas Chromatograph
Column : 4%Carbowax 20M + 0.8%KOH (2 mm ϕ \times 2 m)
Column Temperature : 60° C
Flow Rate : 10 mL/min
Detector : FID (Flame Ionization Detector)
Injection Volume : 250 μ L

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
2009.11.19	1	0.943	100
2011.02.24	1	0.956	100

Result: Gas chromatography indicated one major peak (peak No.1) analyzed on 2009.11.19 and one major peak (peak No.1) analyzed on 2011.2.24.
No new trace impurity peak in the test substance analyzed on 2011.2.24 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 2-YEAR INHALATION STUDY OF
METHYLAMINE

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 2-YEAR
INHALATION STUDY OF METHYLAMINE

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 ± 2.6	743.0 ± 5.0	12.0
5 ppm	23.1 ± 0.1	52.2 ± 1.7	740.7 ± 5.0	12.0
15 ppm	23.0 ± 0.1	51.0 ± 1.7	741.4 ± 4.9	12.0
45 ppm	23.1 ± 0.1	49.8 ± 2.1	748.2 ± 5.7	12.1

APPENDIX 3

METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-YEAR INHALATION STUDY OF METHYLAMINE

METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY
IN THE 2-YEAR INHALATION STUDY OF METHYLAMINE

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	Azobilirubin 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	0
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.)