メチルアミンのラットを用いた
吸入による13週間毒性試験報告書

試験番号：0701

APPENDICES

APPENDICES

APPENDIX 1 - 1

IDENTITY OF METHYLAMINE

IN THE 13-WEEK INHALATION STUDY

IDENTITY OF METHYLAMINE IN THE 13-WEEK INHALATION STUDY

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

Lot No. : M70124

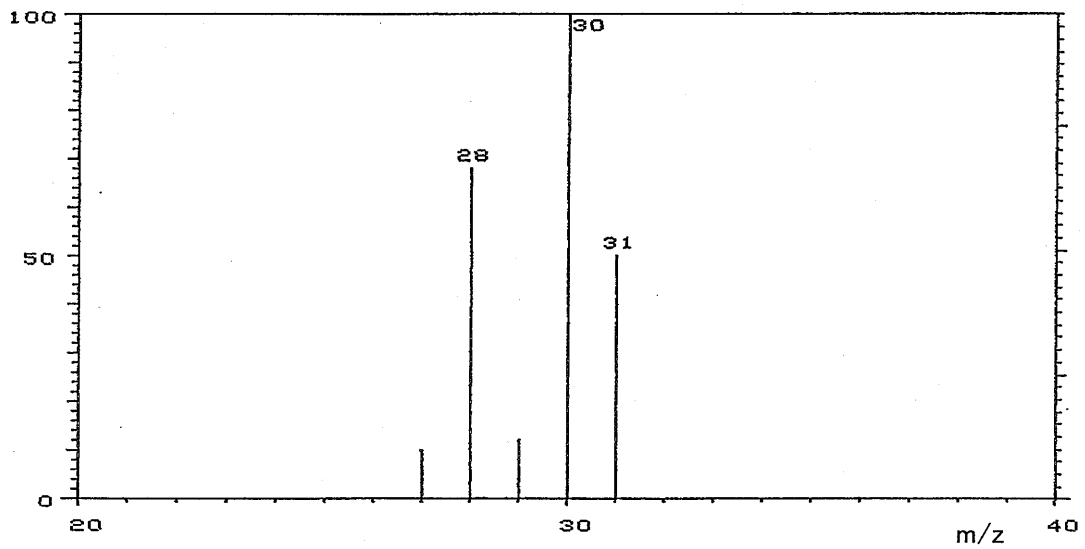
1. Spectral Data

Mass Spectrometry

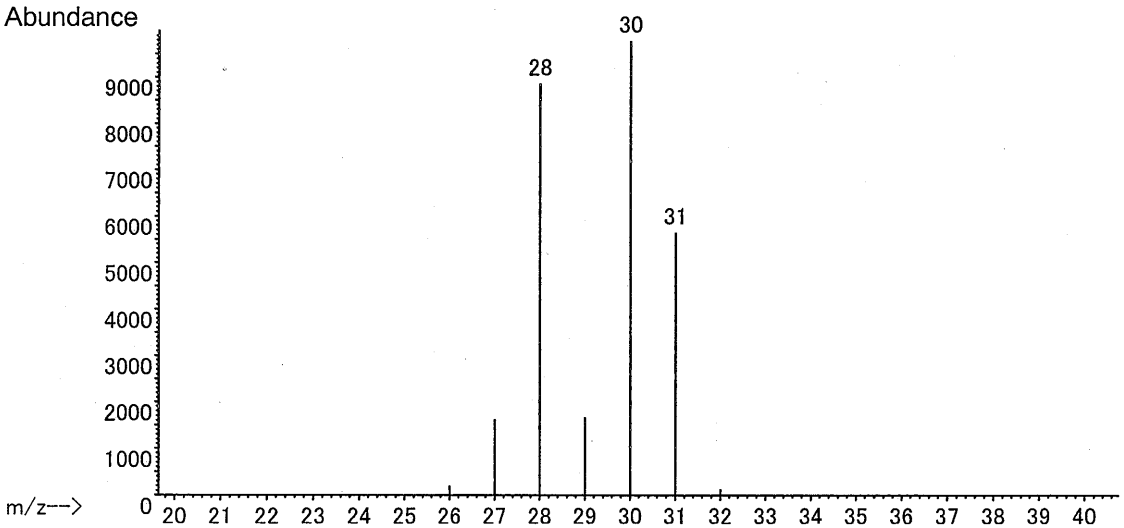
Instrument : Hitachi M-80B Mass Spectrometer

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.

APPENDIX 1 - 2

STABILITY OF METHYLAMINE

IN THE 13-WEEK INHALATION STUDY

STABILITY OF METHYLAMINE IN THE 13-WEEK INHALATION STUDY

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

Lot No. : M70124

1. Gas Chromatography

Instrument : Agilent Technologies 5890A Gas Chromatograph

Column : 4%Carbowax 20M + 0.8%KOH (2 mmϕ × 2 m)

Column Temperature: 60° C

Flow Rate : 10 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 250 μL

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
2007.10.16	1	0.916	100
2008.01.18	1	0.914	100

Result: Gas chromatography indicated one major peak (peak No.1) analyzed on 2007.10.16 and one major peak (peak No.1) analyzed on 2008.1.18. No new trace impurity peak in the test substance analyzed on 2008.1.18 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 13-WEEK INHALATION STUDY OF METHYLAMINE

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 13-WEEK INHALATION STUDY OF METHYLAMINE

Group Name	Temperature (℃) Mean ± S.D.	Humidity (%) Mean ± S.D.	Ventilation Rate (L/min) Mean ± S.D.	Air Change (time/h) Mean
Control	22.7 ± 0.3	54.8 ± 0.8	212.4 ± 1.0	12.0
10 ppm	22.6 ± 0.3	50.3 ± 1.6	212.5 ± 0.8	12.0
20 ppm	22.5 ± 0.4	53.1 ± 1.7	212.2 ± 0.9	12.0
40 ppm	22.6 ± 0.3	51.4 ± 1.5	212.6 ± 0.9	12.0
80 ppm	22.6 ± 0.3	49.9 ± 2.1	212.3 ± 1.0	12.0
160 ppm	22.5 ± 0.3	52.3 ± 1.6	212.4 ± 0.9	12.0

APPENDIX 3

METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 13-WEEK INHALATION STUDY OF METHYLAMINE

METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 13-WEEK INHALATION STUDY OF METHYLAMINE

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 activated method [2]	sec	1
White blood cell(WBC)	Light scattering method [1]	$\times 10^3/\mu L$	2
Differential WBC	Pattern recognition method [3] (Wright staining)	%	0
Biochemistry			
Total protein(TP)	Biuret method [4]	g/dL	1
Albumin (Alb)	BCG method [4]	g/dL	1
A/G ratio	Calculated as Alb/(TP−Alb) [4]	−	1
T-bilirubin	Azobilirubin method [4]	mg/dL	2
Glucose	GlcK·G-6-PDH method [4]	mg/dL	0
T-cholesterol	CE·COD·POD method [4]	mg/dL	0
Triglyceride	MGLP·GK·GPO·POD method [4]	mg/dL	0
Phospholipid	PLD·ChOD·POD method [4]	mg/dL	0
Aspartate aminotransferase (AST)	JSCC method [4]	IU/L	0
Alanine aminotransferase (ALT)	JSCC method [4]	IU/L	0
Lactate dehydrogenase (LDH)	SFBC method [4]	IU/L	0
Alkaline phosphatase (ALP)	GSCC method [4]	IU/L	0
γ-Glutamyl transpeptidase (γ-GTP)	JSCC method [4]	IU/L	0
Creatine kinase (CK)	JSCC method [4]	IU/L	0
Urea nitrogen	Urease·GLDH method [4]	mg/dL	1
Creatinine	Jaffé method [4]	mg/dL	1
Sodium	Ion selective electrode method [4]	mEq/L	0
Potassium	Ion selective electrode method [4]	mEq/L	1
Chloride	Ion selective electrode method [4]	mEq/L	0
Calcium	OCPC method [4]	mg/dL	1
Inorganic phosphorus	PNP·XOD·POD method [4]	mg/dL	1

1) Automatic blood cell analyzer (ADVIA120 : Siemens Healthcare Diagnostics Inc.)
2) Automatic coagulometer (Sysmex CA-5000 : Sysmex Corporation)
3) Automatic blood cell differential analyzer (MICROX HEG-120NA : OMRON Corporation)
4) Automatic analyzer (Hitachi 7080 : Hitachi,Ltd.)