アクロレイ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：0817

APPENDICES

APPENDICES

APPENDIX 1-1

IDENTITY OF ACROLEIN IN THE INHALATION CARCINOGENICITY STUDY

IDENTITY OF ACROLEIN IN THE INHALATION CARCINOGENICITY STUDY

Test Substance : Acrolein (Tokyo Chemical Industry Co., Ltd.)

Lot No. : FNRHH

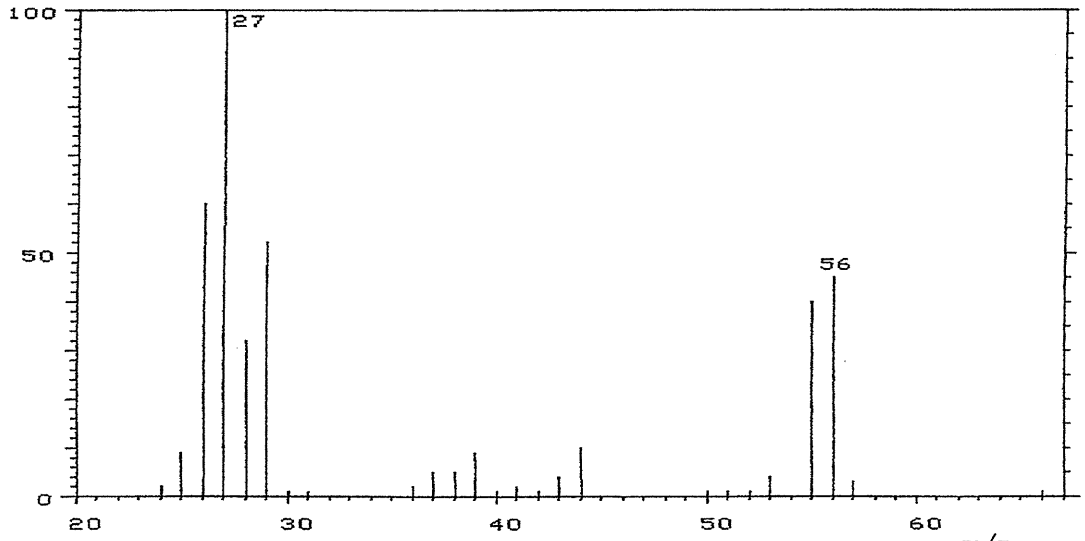
1. Spectral Data

Mass Spectrometry

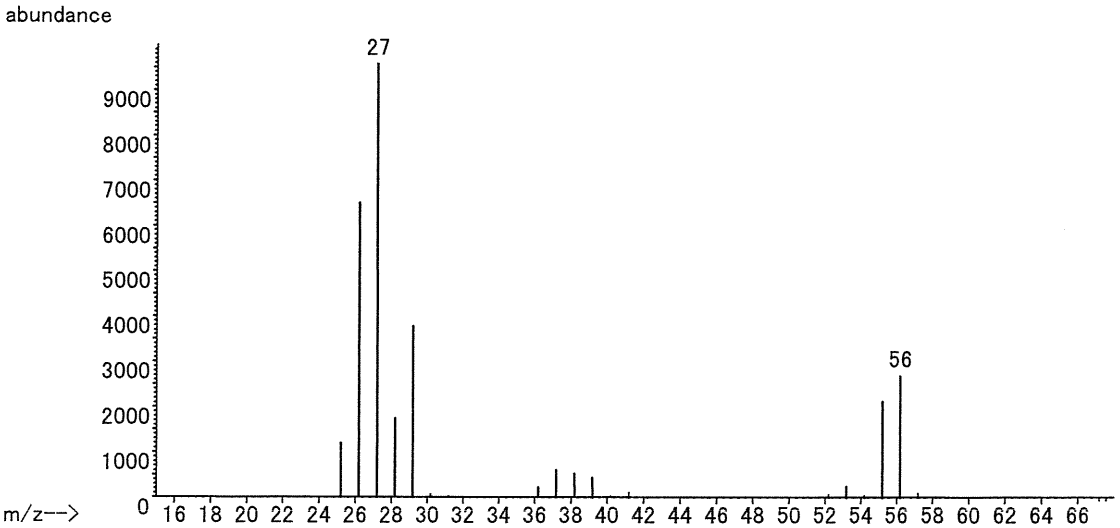
Instrument : Hitachi M-80B Mass Spectrometer

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 acrolein by mass spectrum.

2. Impurity

Instrument : Agilent Technologies 5890A Gas Chromatograph

Column : INNOWAX (0.53 mmϕ × 60 m)

Column Temperature: 60° C

Flow Rate : 10 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μL

Sample Name	Peak No.	Area (%)	Peak Name
Test Substance	1	1.42	Acetaldehyde
	2	98.58	Acrolein

Result: Gas chromatography indicated one major peak (peak No. 2) and one impurity. The impurity (peak No. 1) was identified as acetaldehyde by comparing GC-MS with that of standard sample. The amount of acetaldehyde in the test substance was 1.42% (The quantity value by the standard sample was 1.37%.) with a gas chromatograph.

3. Conclusion: The test substance was identified as acrolein by mass spectrum. Gas chromatography indicated one major peak (acrolein) and one impurity. The impurity was acetaldehyde in the test substance.

APPENDIX 1-2

STABILITY OF ACROLEIN IN THE INHALATION CARCINOGENICITY STUDY

STABILITY OF ACROLEIN IN THE INHALATION CARCINOGENICITY STUDY

Test Substance : Acrolein (Tokyo Chemical Industry Co., Ltd.)

Lot No. : FNRHH

1. Gas Chromatography

Instrument : Agilent Technologies 5890A Gas Chromatograph

Column : INNOWAX (0.53 mmϕ × 60 m)

Column Temperature: 60° C

Flow Rate : 10 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μL

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
2013.02.01	1	2.005	1.42
	2	2.668	99.58
2015.02.23	1	1.997	1.28
	2	2.640	98.72

Result: Gas chromatography indicated one major peak (peak No.2) and one impurity (peak No. 1 < 2.0% of total area) analyzed on 2013.2.1 and one major peak (peak No.2) and one impurity (peak No. 1 < 2.0% of total area) analyzed on 2015.2.23. No new trace impurity peak in the test substance analyzed on 2015.2.23 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 ACROLEIN

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER
IN THE INHALATION CARCINOGENICITY STUDY OF ACROLEIN

Group Name	Temperature (℃) Mean ± S.D.	Humidity (%) Mean ± S.D.	Ventilation Rate (L/min) Mean ± S.D.	Air Change (time/h) Mean
Control	22.9 ± 0.0	52.9 ± 1.2	737.1 ± 5.8	12.0
0.1 ppm	22.9 ± 0.0	52.5 ± 0.8	737.8 ± 5.9	12.0
0.4 ppm	23.0 ± 0.0	53.3 ± 1.0	736.6 ± 5.5	11.9
1.6 ppm	23.0 ± 0.0	54.1 ± 1.3	738.1 ± 5.5	12.0

APPENDIX 3

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

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

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
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 Alb/(TP−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.)