

アリルアルコール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：0902

# APPENDICES

## APPENDICES

- APPENDIX 1-1 IDENTITY OF ALLYL ALCHOL IN THE 13-WEEK  
INHALATION STUDY
- APPENDIX 1-2 STABILITY OF ALLYL ALCHOL IN THE 13-WEEK  
INHALATION STUDY
- APPENDIX 2 ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER  
IN THE 13-WEEK INHALATION STUDY OF ALLYL ALCHOL
- APPENDIX 3 METHODS, UNITS AND DECIMAL PLACE FOR HEMATOLOGY  
AND BIOCHEMISTRY IN THE 13-WEEK INHALATION STUDY  
OF ALLYL ALCHOL

**APPENDIX 1 - 1**

**IDENTITY OF ALLYL ALCOHOL IN THE 13-WEEK  
INHALATION STUDY**

## IDENTITY OF ALLYL ALCOHOL IN THE 13-WEEK INHALATION STUDY

Test Substance : Allyl alcohol (Wako Pure Chemical Industries, Ltd.)

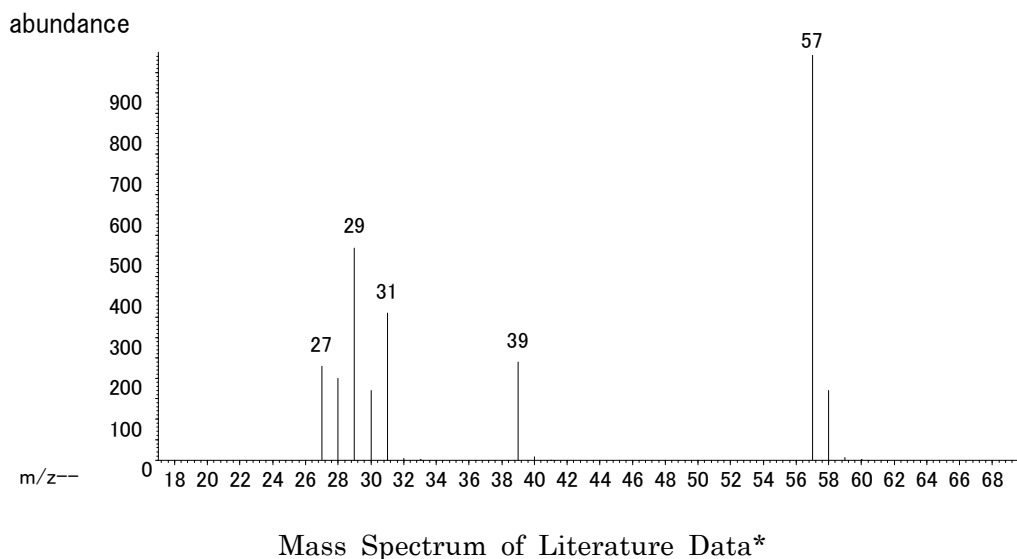
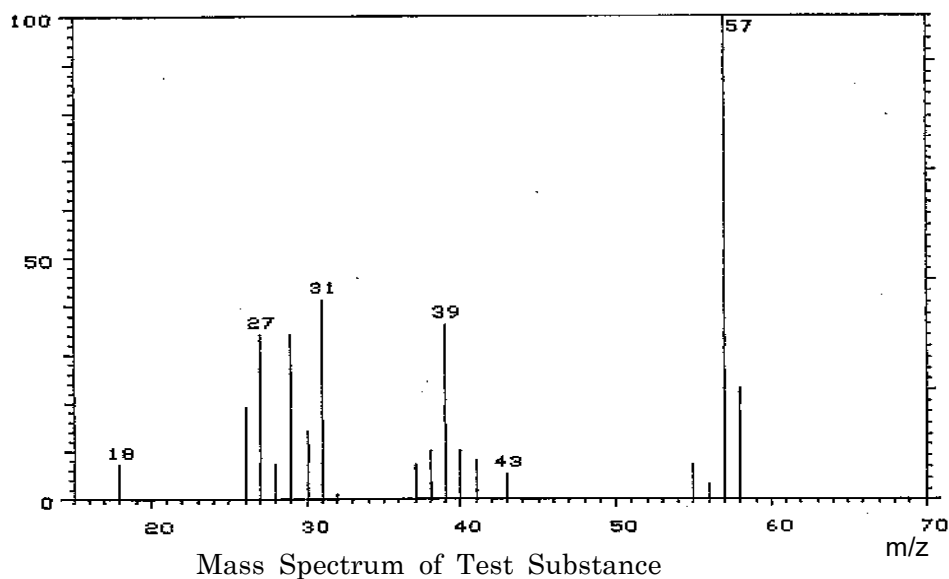
Lot No. : TWR6089

## 1. Mass Spectrometry

Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



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 allyl alcohol by mass spectrum.

**APPENDIX 1 - 2**

**STABILITY OF ALLYL ALCOHOL IN THE 13-WEEK  
INHALATION STUDY**

## STABILITY OF ALLYL ALCOHOL IN THE 13-WEEK INHALATION STUDY

Test Substance : Allyl alcohol (Wako Pure Chemical Industries, Ltd.)

Lot No. : TWR6089

## 1. Gas Chromatography

Instrument : Agilent Technologies 5890A Gas Chromatograph

Column : INNOWAX (0.53 mm  $\phi$   $\times$  60 m)

Column Temperature : 100 °C

Flow Rate : 5 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1  $\mu$ L

Date Analyzed	Peak No.	Retention Time (min)	Area (%)
2017.11.21	1	4.820	100
2018.02.23	1	4.821	100

Result: Gas chromatography indicated one major peak (peak No.1) analyzed on 2017.11.21 and one major peak (peak No.1) analyzed on 2018.2.23. No new trace impurity peak in the test substance analyzed on 2018.2.23 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 13-WEEK INHALATION STUDY OF  
ALLYL ALCOHOL**

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER  
IN THE 13-WEEK INHALATION STUDY OF ALLYL ALCOHOL

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 ± 0.2	58.8 ± 0.5	212.9 ± 0.7	12.1
1.6 ppm	23.0 ± 0.2	57.7 ± 0.7	212.7 ± 0.8	12.0
3.1 ppm	23.1 ± 0.1	57.4 ± 0.7	213.1 ± 0.7	12.1
6.3 ppm	22.9 ± 0.1	59.0 ± 0.7	213.2 ± 0.7	12.1
12.5 ppm	23.1 ± 0.1	56.8 ± 0.6	212.6 ± 0.9	12.0
25 ppm	22.7 ± 0.2	56.05 ± 0.9	213.0 ± 0.7	12.1



## **APPENDIX 3**

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

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

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

1) Automated Hematology Analyzer (XN-2000V : Sysmex Corporation)

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