

# **Scientific Documentation**

# Methyl Alcohol, NF

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp 769 Jersey Avenue New Brunswick, NJ 08901 Phone 732.214.1300





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# **Specification for Methyl Alcohol, NF (ME151)**

Item Number	ME151
Item	Methyl Alcohol, NF
CAS Number	67-56-1
Molecular Formula	CH <sub>3</sub> OH
Molecular Weight	32.04
MDL Number	
Synonyms	Methyl Alcohol ; Methanol

Test	Specification	
	Min	Max
APPEARANCE		
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD	
ASSAY	99.5 %	
ACIDITY		0.45 ml
ALKALINITY (AS AMMONIA)		3 ppm
WATER DETERMINATION		0.1 %
NONVOLATILE RESIDUE		0.001 % (w/w)
READILY CARBONIZABLE SUBSTANCES	NO DISCOLORATION	
READILY OXIDIZABLE SUBSTANCES	PINK COLOR REMAINS	
ACETONE & ALDEHYDE(as ACETONE)		0.003 %
ELEMENTAL IMPURITIES	AS REPORTED	
CERTIFIED KOSHER		
RETEST DATE		
DATE OF MANUFACTURE		
MONOGRAPH EDITION		
RESIDUAL SOLVENTS:	AS REPORTED	

Spectrum Chemical Mfg Corp

769 Jersey Ave. 14422 S. San Pedro St.

New Brunswick, NJ 08901 Gardena, CA 90248

732.214.1300 310.516.8000



# **Certificate Of Analysis**

Item Number	ME151	Lot Number	1ML0159
Item	Methyl Alcohol, NF	CAS Number	67-56-1
Molecular Formula	CH <sub>3</sub> OH	Molecular Weight	32.04

TECT	SPECIFICATION		DECLUT	
TEST	MIN	MAX	RESULT	
APPEARANCE			CLEAR COLORLESS LIQUID	
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD	
ASSAY	99.5 %		99.99 %	
ACIDITY		0.45 ml	0.25 ml	
ALKALINITY (AS AMMONIA)		3 ppm	<3 ppm	
WATER DETERMINATION		0.1 %	0.03 %	
NONVOLATILE RESIDUE		0.001 % (w/w)	<0.001 %	
READILY CARBONIZABLE SUBSTANCES	NO DISCOLORATION		NO DISCOLORATION	
READILY OXIDIZABLE SUBSTANCES	PINK COLOR REMAINS		PINK COLOR REMAINS	
ACETONE & ALDEHYDE(as ACETONE)		0.003 %	<0.003 %	
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT	
CERTIFIED KOSHER			CERTIFIED KOSHER	
RETEST DATE			25-JUN-2028	
DATE OF MANUFACTURE			27-JUN-2023	
MONOGRAPH EDITION			(USP-NF) 2023	
RESIDUAL SOLVENTS:	AS REPORTED			
CLASS 3 (solvent) / ETHANOL			<5000 ppm	

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 22-DEC-23 15:00:33

Spectrum Chemical Mfg Corp 14422 South San Pedro Street Gardena 90248 CA



Certificate of Analysis Results Approved By:

SHANSEN Selin Hansen 29-DEC-23 12:12:37

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

# SPECTION®

# **spectrum**°

Revision date 12-January-2022

**Revision Number** 5

#### 1. Identification

**Product identifier** 

Product Name METHYL ALCOHOL, NF

Other means of identification

Product Code(s) ME151

UN/ID no UN1230

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use

No information available

Restrictions on use No information available

Details of the supplier of the safety data sheet

**Supplier Address** 

Spectrum Chemical Mfg. Corp. 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

# 2. Hazard(s) identification

#### Classification

Acute toxicity - Oral	Category 3
Acute toxicity - Dermal	Category 3
Acute toxicity - Inhalation (Vapors)	Category 3
Serious eye damage/eye irritation	Category 2A
Reproductive toxicity	Category 2
Flammable liquids	Category 2

#### Hazards not otherwise classified (HNOC)

Not applicable

#### **Label elements**

Danger

#### Hazard statements

Toxic if swallowed

Toxic in contact with skin

Toxic if inhaled

Causes serious eye irritation

Suspected of damaging fertility or the unborn child

Highly flammable liquid and vapor



Appearance clear Physical state Liquid Odor Alcohol

#### **Precautionary Statements - Prevention**

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Wear protective gloves/protective clothing/eye protection/face protection

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

Avoid breathing dust/fume/gas/mist/vapors/spray

Use only outdoors or in a well-ventilated area

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking

Keep container tightly closed

Ground/bond container and receiving equipment

Use explosion-proof electrical/ventilating/lighting/.?/equipment

Use only non-sparking tools

Take precautionary measures against static discharge

Keep cool

#### **Precautionary Statements - Response**

IF exposed or concerned: Get medical advice/attention

Specific treatment (see .? on this label)

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

If eye irritation persists: Get medical advice/attention Call a POISON CENTER or doctor if you feel unwell

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower

Wash contaminated clothing before reuse

IF INHALED: Remove person to fresh air and keep comfortable for breathing

Call a POISON CENTER or doctor

IF SWALLOWED: Immediately call a POISON CENTER or doctor

Rinse mouth

In case of fire: Use CO2, dry chemical, or foam to extinguish

#### **Precautionary Statements - Storage**

Store locked up.

Store in a well-ventilated place. Keep container tightly closed

#### **Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

#### Other information

No information available.

# 3. Composition/information on ingredients

#### Substance

Chemical name	CAS No	Weight-%	Trade secret
Methyl Alcohol	67-56-1	100	*

<sup>\*</sup>The exact percentage (concentration) of composition has been withheld as a trade secret.

# 4. First-aid measures

#### Description of first aid measures

Show this safety data sheet to the doctor in attendance. Immediate medical attention is **General advice** 

required.

Inhalation Remove to fresh air. If breathing has stopped, give artificial respiration. Get medical

> attention immediately. Immediate medical attention is required. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If

breathing is difficult, (trained personnel should) give oxygen.

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep Eye contact

> eye wide open while rinsing. Do not rub affected area. Get immediate medical advice/attention. Remove contact lenses, if present and easy to do. Continue rinsing.

Skin contact Wash off immediately with soap and plenty of water while removing all contaminated

clothes and shoes. Get immediate medical advice/attention.

Ingestion Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water.

Never give anything by mouth to an unconscious person. Get immediate medical

advice/attention.

Self-protection of the first aider Remove all sources of ignition. Ensure that medical personnel are aware of the material(s)

involved, take precautions to protect themselves and prevent spread of contamination. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Do not breathe vapor or mist.

Most important symptoms and effects, both acute and delayed

**Symptoms** May cause redness and tearing of the eyes, Burning sensation, Coughing and/or

wheezing. Difficulty in breathing.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

#### 5. Fire-fighting measures

Dry chemical. Carbon dioxide (CO2). water spray. Alcohol resistant foam. **Suitable Extinguishing Media** Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams.

Specific hazards arising from the

chemical

risk of ignition. Keep product and empty container away from heat and sources of ignition. In the event of fire, cool tanks with water spray. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

**Hazardous combustion products** Carbon Monoxide, Carbon Dioxide.

**Explosion data** 

Sensitivity to mechanical impact none.

Sensitivity to static discharge

Special protective equipment for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

gear. Use personal protection equipment.

#### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

yes.

Evacuate personnel to safe areas. Use personal protective equipment as required. See Personal precautions

> section 8 for more information. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Do not touch or walk through spilled material. Do not breathe

vapor or mist.

Other information Ventilate the area. Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Do not touch or walk through spilled material. A vapor

suppressing foam may be used to reduce vapors. Dike far ahead of spill to collect runoff water. Keep out of drains, sewers, ditches and waterways. Absorb with earth, sand or other

non-combustible material and transfer to containers for later disposal.

Take precautionary measures against static discharges. Dam up. Soak up with inert Methods for cleaning up

absorbent material. Pick up and transfer to properly labeled containers.

# 7. Handling and storage

#### Precautions for safe handling

Advice on safe handling

Use personal protection equipment. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use grounding and bonding connection when transferring this material to prevent static discharge, fire or explosion. Use spark-proof tools and explosion-proof equipment. Keep in an area equipped with sprinklers. Use according to package label instructions. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Take off contaminated clothing and wash before reuse. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Do not breathe vapor or mist. In case of insufficient ventilation, wear suitable respiratory equipment. Handle product only in closed system or provide appropriate exhaust ventilation.

#### Conditions for safe storage, including any incompatibilities

**Storage Conditions** 

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep in properly labeled containers. Do not store near combustible materials. Keep in an area equipped with sprinklers. Store in accordance with the particular national regulations. Store in accordance with local regulations. Keep out of the reach of children. Store locked up.

# 8. Exposure controls/personal protection

Control parameters

**Exposure Limits** 

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Methyl Alcohol	No data available	200 ppm TWA	-
67-56-1		260 mg/m³ TWA	

#### **Appropriate engineering controls**

**Engineering controls Showers** 

> Eyewash stations Ventilation systems.

#### Individual protection measures, such as personal protective equipment

Eye/face protection Tight sealing safety goggles.

Wear suitable gloves. Impervious gloves. Hand protection

Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron. Skin and body protection

Antistatic boots.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

**General hygiene considerations** Do not eat, drink or smoke when using this product. Contaminated work clothing should not

be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Remove and wash contaminated clothing and gloves, including the inside, before re-use.

None known

Do not breathe vapor or mist.

# 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Liquid **Appearance** clear Colorless Color Odor Alcohol

No information available Odor threshold

**Property** Values Remarks • Method

no data available None known pН None known Melting point / freezing point -97.8 °C / -144 °F 64 - 65 °C / 147.2 - 149 °F Boiling point / boiling range None known Flash point 11 °C / 51.8 °F None known no data available **Evaporation rate** None known Flammability (solid, gas) no data available None known Flammability Limit in Air None known

Upper flammability or explosive 36.5 %

limits

Lower flammability or explosive 6 %

limits

Vapor pressure 12.3 - 12.8 None known Vapor density 1.11 None known 0.7866 - 0.7915 Relative density None known Water solubility No data available None known Solubility(ies) no data available None known **Partition coefficient** No data available None known

Autoignition temperature **Decomposition temperature** 

None known Kinematic viscosity no data available None known Dynamic viscosity No data available None known

no data available

Other information

Explosive propertiesNo information availableOxidizing propertiesNo information availableSoftening pointNo information available

Molecular weight 32.04

VOC Content (%)
Liquid Density
No information available
No information available
No information available

# 10. Stability and reactivity

**Reactivity** No information available.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions 
None under normal processing.

**Conditions to avoid** Heat, flames and sparks. Excessive heat.

**Incompatible materials**None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

# 11. Toxicological information

#### Information on likely routes of exposure

Product Information .

**Inhalation** Specific test data for the substance or mixture is not available. May cause irritation of

respiratory tract. Toxic by inhalation. (based on components).

Eye contact Specific test data for the substance or mixture is not available. Causes serious eye irritation.

(based on components). May cause redness, itching, and pain.

**Skin contact** Specific test data for the substance or mixture is not available. May cause irritation.

Prolonged contact may cause redness and irritation. Toxic in contact with skin. (based on

components).

**Ingestion** Specific test data for the substance or mixture is not available. Ingestion may cause

gastrointestinal irritation, nausea, vomiting and diarrhea. Toxic if swallowed. (based on

components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms May cause redness and tearing of the eyes. Coughing and/ or wheezing. Difficulty in

breathing.

**Acute toxicity** 

Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Methyl Alcohol	5628 mg/kg (Rat)	15800 mg/kg (Rabbit)	83.2 mg/L (Rat) 4 h
67-56-1			-

#### Delayed and immediate effects as well as chronic effects from short and long-term exposure

**Skin corrosion/irritation** May cause skin irritation.

Serious eye damage/eye irritation Classification based on data available for ingredients. Causes serious eye irritation.

Respiratory or skin sensitization No information available.

**Germ cell mutagenicity**Carcinogenicity
No information available.
No information available.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Reproductive toxicity Contains a known or suspected reproductive toxin. Classification based on data available

for ingredients. Suspected of damaging fertility or the unborn child.

**STOT - single exposure**STOT - repeated exposure
No information available.
No information available.

Target organ effects respiratory system, Eyes, Skin, central nervous system, Gastrointestinal tract (GI).

**Aspiration hazard** No information available.

Other adverse effects No information available.

Interactive effects No information available.

# 12. Ecological information

**Ecotoxicity** 

	•			
Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
			microorganisms	
Methyl Alcohol	-	LC50: 13500 -	-	-
67-56-1		17600mg/L (96h,		
		Lepomis macrochirus)		
		LC50: 18 - 20mL/L (96h,		
		Oncorhynchus mykiss)		
		LC50: 19500 -		
		20700mg/L (96h,		
		Oncorhynchus mykiss)		
		LC50: =28200mg/L (96h,		
		Pimephales promelas)		
		LC50: >100mg/L (96h,		
		Pimephales promelas)		

Persistence and degradability Bioaccumulation

No information available. Inherently biodegradable.

**Component Information** 

Chemical name	Partition coefficient	
Methyl Alcohol	-0.77	
67-56-1		

Other adverse effects No information available.

#### 13. Disposal considerations

#### Waste treatment methods

Waste from residues/unused

products

Should not be released into the environment. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging

Empty containers pose a potential fire and explosion hazard. Do not cut, puncture of weld containers.

# 14. Transport information

DOT

UN/ID no UN1230

Proper Shipping Name: Methanol

Hazard class 3
Subsidiary Class 6.1
Packing group: II

Special Provisions IB2, T7, TP2

Marine Pollutant Severe Marine Pollutant UN1230, Methanol, 3 (6.1), II

**Emergency Response Guide** 131

Number

#### **TDG**

UN-No: UN1230
Proper Shipping Name: Methanol
Hazard class 3
Subsidiary Class 6.1
Packing Group: II

**Description:** UN1230, Methanol, 3 (6.1), II

#### **MEX**

UN-No UN1230
Proper Shipping Name Methanol
Hazard class 3
Subsidiary Class 6.1
Special Provisions 279
Packing Group II

**Description** UN1230, Methanol, 3 (6.1), II

#### ICAO (air)

UN-No: UN1230
Proper Shipping Name: Methanol
Hazard class 3
Subsidiary hazard class 6.1
Packing Group: II
Special Provisions A113

**Description:** UN1230, Methanol, 3 (6.1), II

#### IATA

UN number UN1230
Proper Shipping Name: Methanol
Transport hazard class(es) 3
Subsidiary hazard class
Packing group II

**Description:** UN1230, Methanol, 3 (6.1), II

#### **IMDG**

**UN** number UN1230 Proper shipping name Methanol Transport hazard class(es) 3 Subsidiary hazard class 6.1 Packing group Ш EmS-No F-E, S-D **Special Provisions** 279 Marine pollutant NP1

**Description** UN1230, Methanol, 3 (6.1), II, (11°C c.c.)

#### <u>RID</u>

UN number
UN1230
Proper Shipping Name: Methanol
Transport hazard class(es)
Packing group
Classification code
Special Provisions
UN1230
II
FT1
279

**Description:** UN1230, Methanol, 3 (6.1), II

**Labels** 3 + 6.1

#### <u>ADR</u>

UN number 1230 Proper Shipping Name: Methanol

Transport hazard class(es) 3
Subsidiary hazard class 6.1
Packing group II
Classification code FT1
Tunnel restriction code (D/E)
Special Provisions 279

**Description:** 1230, Methanol, 3 (6.1), II, (D/E)

**Labels** 3 + 6.1

ADN

UN/ID No UN1230 Proper shipping name Methanol

Transport hazard class(es) 3
Packing Group II
Classification code FT1
Special Provisions 279, 802

**Description** UN1230, Methanol, 3 (+ 6.1), II

Hazard label(s) 3 + 6.1Limited quantity (LQ) 1 L

ventilation VE01, VE02 Equipment Requirements PP, EP, EX, TOX, A

# 15. Regulatory information

#### **International Inventories**

TSCA Complies

DSL/NDSL Complies EINECS/ELINCS Complies

**ENCS** This product complies with ENCS: **IECSC** This product complies with China:

KECL Complies Complies

AICS All the constituents of this material are listed on the Australian Inventory of Chemical

Substances (AICS).

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances **IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

#### **US Federal Regulations**

#### **SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

Chemical name	SARA 313 - Threshold Values %
Methyl Alcohol - 67-56-1	1.0

#### SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

#### **CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### **CERCLA**

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

	Chemical name	Hazardous Substances RQs	Extremely Hazardous Substances RQs
1	Methyl Alcohol	5000 lb final RQ	-
	67-56-1	2270 kg final RQ	

#### **US State Regulations**

#### **California Proposition 65**

This product contains the following Proposition 65 chemicals:.

Chemical name	California Proposition 65
Methyl Alcohol - 67-56-1	developmental toxicity

#### **U.S. State Right-to-Know Regulations**

This product does not contain any substances regulated under applicable state right-to-know regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Methyl Alcohol	1222	Present	Environmental hazard
67-56-1			

#### U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

#### 16. Other information

NFPA

Health hazards 4

Flammability 3

Instability 0

Physical and chemical properties -

HMIS

Health hazards 3 \*

Flammability 3

Physical hazards 0

Personal protection X

Chronic Hazard Star Legend

\* = Chronic Health Hazard

#### Key or legend to abbreviations and acronyms used in the safety data sheet

#### Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL

STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value

#### Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision date 12-January-2022 Revision Note 12-January-2022 No information available.

**Disclaimer** 

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet** 



#### Certification of Compliance with current Good Manufacturing Practices

#### Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
ME151	Methyl Alcohol, NF

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632 Spectrum-New Brunswick, NJ: 2246824

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at <a href="mailto:qualityassurance@spectrumchemical.com">qualityassurance@spectrumchemical.com</a>

Sincerely,

Oralia Chavez

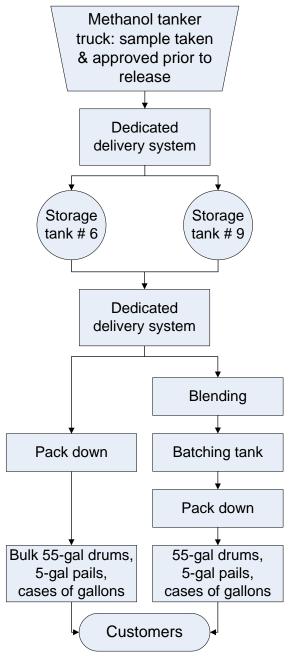
**Quality Assurance Specialist** 

Order Clony



# **Manufacturing Process Flowchart**

# Methyl Alcohol, NF - ME151



#### Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.

732.214.1300

New Brunswick, NJ 08901

14422 S. San Pedro St. Gardena, CA 90248

West Coast Facility:

310.516.8000



# ME151, Methyl Alcohol, NF

#### **Source Statement**

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

#### **BSE/TSE Statement**

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

# **Allergen Statement**

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy

- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

#### **GMO Statement**

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

#### **Melamine Statement**

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

#### **Nitrosamine Statement**

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.



# **Animal Testing Statement**

The above mentioned catalog item has not been tested on animals.

# **Organic Compliance Statement**

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

# **Shelf Life Statement**

The above mentioned catalog item is typically assigned a shelf life of 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

#### **Other Chemicals Statement**

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- Aflatoxins
- Bisphenol A (BPA)
- CMR Substances

- Pesticides
- Phthalates
- Preservatives



RE: Elemental Impurities - Methyl Alcohol, NF (Cat# ME151)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132 WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843



# RE: Residual Solvents - Methyl Alcohol, NF (Cat# ME151)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvent is likely to be present:

Residual Solvent	Class	Expected Concentration
Ethanol	3	< 5000 ppm

No Class 1, Class 2, or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

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# **Label Information**

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.



0000-00-00

Causes damage to central nervous system and eye/optic nerve Causes damage to skin, kidneys, liver, central nervous system and eye/optic nerve through prolonged or repeated exposure Suspected of damaging fertility or the unbrom child.

\* Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Keep away from heat, sparks, open flames, hot surfaces • No smoking • Ground container and receiving equipment • Use explosion-proof equipment • Use only on on-sparking tools • Take precautionary measures against static discharge • Do not eat, drink or smoke when using this product • Wear protective gloves, protective clothing, eye protection, face protection • Do not breathen mist or vapors • Use only outdoors or hor or breathen sit or vapors • Use only outdoors or hor order them is to ryapors • Use only outdoors or hor order them is to ryapors • Use only outdoors or hor order them is to ryapors • Use only outdoors or hor order them is to ryapors • Use only outdoors or hor order them is to ryapors • Use only outdoors or hor order them is to ryapors • Use only outdoors or hor order them is to ryapors • Use only outdoors or hor order them is to ryapors • Use only outdoors or hor order them is to ryapors • Use only outdoors or hor order or hor order or order or order or order or order or order or order order or order o

**KEEP FROM CHILDREN** 

# **ME151** SIZ SY **Methyl Alcohol**

(Methanol) NF

CAS 67-56-1

CAUTION: For manufacturing or laboratory use

Read and understand the label and Safety Data Sheet (SDS) prior to use.

DOT: UN1230, Methanol, 3, PG II

Chemical Emergency: (800)424-9300 www.SpectrumChemical.com

CH<sub>2</sub>OH F.W. 32.04

Assay	Min. 99.5%
MAXIMUM LIMITS	
Acidity	
Alkalinity (as Ammonia)	3 ppm
Water Determination	0.1%
Nonvolatile Residue	0.001% (w/w)
Readily Carbonizable Substances	To pass test
Readily Oxidizable Substances	To pass test
Acetone and Aldehydes (as Acetone	9) 0.003%
Elemental Impurities	As reported
Residual Solvents	To pass test

NON-PHOTOCHEMICALLY REACTIVE

**WARNING:** Reproductive Harmwww.P65Warnings.ca.gov

Lot No. XQ#### R 14/H3GHS

# Spectrum Chemical Mfg Corp

Corporate Headquarters:

New Brunswick, NJ 08901

14422 S. San Pedro St. Gardena, CA 90248

310.516.8000

732.214.1300

769 Jersey Ave.





The following product(s) prepared by the named company are certified kosher with the stated requirements:

# **Spectrum Laboratory Products, Inc.**

S-0032

14422 South San Pedro Street, Gardena, CA 90248 755-769 Jersey Ave. New Brunswick NJ 08901 USA

Product Name ME151, Methyl Alcohol, NF

**Brand** Spectrum

UKD-ID KSAV3-V0R3U37

D/P/M P

Symbol Required KSA

**Special Conditions** 

This certificate expires on **Feb 01, 2025** 

Rabbi Binyomin Lisbon Kashrus Administrator

Placing the KSA logo on products not listed above constitutes an un-authorized use of the KSA symbol, which is a federally registered trademark.