

# **Scientific Documentation**

# Monoethanolamine, 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 Monoethanolamine, NF (M1322)

Item Number	M1322
Item	Monoethanolamine, NF
CAS Number	141-43-5
Molecular Formula	C <sub>2</sub> H <sub>7</sub> NO
Molecular Weight	61.08
MDL Number	
Synonyms	Monoethanolamine ; Ethanolamine

Test	Specification	
	Min	Max
ASSAY	98.0	100.5%
SPECIFIC GRAVITY @ 25°C	1.013	1.016
DISTILLING RANGE (95 %)	167°	173°C
RESIDUE ON IGNITION		0.1%
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION (FTIR)	SPECTRUM MATCHES REFERENCE	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	AS REPORTED	

# Spectrum Chemical Mfg Corp

Corporate Headquarters:West Coast Facility:769 Jersey Ave.14422 S. San Pedro St.New Brunswick, NJ 08901Gardena, CA 90248732.214.1300310.516.8000



# **Certificate Of Analysis**

Item Number	M1322	Lot Number	1ND0185
Item	Monoethanolamine, NF	CAS Number	141-43-5
Molecular Formula	C <sub>2</sub> H <sub>7</sub> NO	Molecular Weight	61.08

TECT	SPECIFICATION		DECLUT	
TEST	MIN	MAX	RESULT	
ASSAY	98.0	100.5%	98.7 %	
SPECIFIC GRAVITY @ 25°C	1.013	1.016	1.015	
DISTILLING RANGE (95 %)	167°	173°C	167° - 173°C	
RESIDUE ON IGNITION		0.1%	0.0 %	
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT	
IDENTIFICATION (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE	
EXPIRATION DATE			30-APR-2025	
DATE OF MANUFACTURE			04-OCT-2023	
APPEARANCE			CLEAR COLORLESS LIQUID	
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS PRESENT	
MONOGRAPH EDITION			(USP-NF) 2023	

Certificate of Analysis Results Entered By:

AMENDEZ Ana Mendez 22-APR-24 11:44:20

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



Certificate of Analysis Results Approved By:

HBERMUDEZ Hernan Bermudez 23-APR-24 09:35:49

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.

# SAFETY DATA SHEET SPECTRUM®



Revision date 09-September-2020

**Revision Number** 2

## 1. Identification

**Product identifier** 

Product Name MONOETHANOLAMINE, NF

Other means of identification

Product Code(s) M1322

UN/ID no UN2491

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 4
Acute toxicity - Dermal	Category 4
Acute toxicity - Inhalation (Gases)	Category 4
Acute toxicity - Inhalation (Vapors)	Category 4
Acute toxicity - Inhalation (Dusts/Mists)	Category 4
Skin corrosion/irritation	Category 1 Sub-category B
Serious eye damage/eye irritation	Category 1
Skin sensitization	Category 1B
Flammable liquids	Category 4

# Hazards not otherwise classified (HNOC)

Not applicable

#### **Label elements**

#### Danger

#### Hazard statements

Harmful if swallowed

Harmful in contact with skin

Harmful if inhaled

Causes severe skin burns and eye damage

May cause an allergic skin reaction

Combustible liquid



Appearance viscous Physical state Liquid Odor unpleasant

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

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

Use only outdoors or in a well-ventilated area

Do not breathe dusts or mists

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

Contaminated work clothing must not be allowed out of the workplace

Keep away from flames and hot surfaces. - No smoking

# **Precautionary Statements - Response**

Immediately call a POISON CENTER or doctor

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing Immediately call a POISON CENTER or doctor

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

If skin irritation or rash occurs: Get medical advice/attention

Wash contaminated clothing before reuse

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

Immediately call a POISON CENTER or doctor

IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

Rinse mouth

Do NOT induce vomiting

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 cool

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

Dispose of contents/container to an approved waste disposal plant

#### Unknown acute toxicity

#### Other information

Harmful to aquatic life with long lasting effects. Harmful to aquatic life.

# 3. Composition/information on ingredients

#### Substance

Chemical name	CAS No	Weight-%	Trade secret
Ethanolamine	141-43-5	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

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

required.

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

attention immediately. 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. Delayed pulmonary edema may occur. Get immediate medical

advice/attention.

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

eye wide open while rinsing. Do not rub affected area. Remove contact lenses, if present

and easy to do. Continue rinsing. Get immediate medical advice/attention.

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

clothes and shoes. Get immediate medical advice/attention. May cause an allergic skin

reaction.

**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. Avoid contact with skin, eyes or clothing. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Avoid breathing vapors or mists. Use personal protective

equipment as required. See section 8 for more information.

Most important symptoms and effects, both acute and delayed

**Symptoms** Burning sensation. Itching. Rashes. Hives. Coughing and/ or wheezing. Difficulty in

breathing.

Indication of any immediate medical attention and special treatment needed

**Note to physicians** Product is a corrosive material. Use of gastric lavage or emesis is contraindicated.

Possible perforation of stomach or esophagus should be investigated. Do not give chemical antidotes. Asphyxia from glottal edema may occur. Marked decrease in blood pressure may occur with moist rales, frothy sputum, and high pulse pressure. May cause

sensitization in susceptible persons. Treat symptomatically.

#### 5. Fire-fighting measures

Suitable Extinguishing Media
Large Fire

Dry chemical. Carbon dioxide (CO2). water spray. Alcohol resistant foam.

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

Keep product and empty container away from heat and sources of ignition. In the event of fire, cool tanks with water spray. The product causes burns of eyes, skin and mucous membranes. Thermal decomposition can lead to release of irritating gases and vapors.

Product is or contains a sensitizer. May cause sensitization by skin contact.

Hazardous combustion products Carbon dioxide (CO2). Hydrocarbons.

**Explosion data** 

Sensitivity to mechanical impact none.

Sensitivity to static discharge

ves.

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

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

section 8 for more information. Take precautionary measures against static discharges. Do not touch or walk through spilled material. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Attention! Corrosive material. Keep people away from and upwind of

spill/leak. Avoid breathing vapors or mists.

Other information 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. Dike far

ahead of liquid spill for later disposal.

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

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. Do not breathe vapor or mist. Keep away from heat,

hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharges. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. In case of insufficient ventilation, wear suitable respiratory equipment. Handle product only in closed system or provide appropriate exhaust ventilation. Do not eat, drink or smoke when using

this product. Take off contaminated clothing and wash before reuse.

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

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from **Storage Conditions** 

heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep in properly labeled containers. Store in accordance with the particular national regulations. Store in accordance with local regulations. Keep out of the reach of children. Store locked up. Protect from moisture. Store away from other materials.

# 8. Exposure controls/personal protection

#### Control parameters

#### **Exposure Limits**

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Ethanolamine	No data available	3 ppm TWA	-
141-43-5		6 mg/m <sup>3</sup> TWA	

#### Appropriate engineering controls

Showers **Engineering controls** 

Eyewash stations Ventilation systems.

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

**Eye/face protection** Tight sealing safety goggles. Face protection shield.

**Hand protection** Wear suitable gloves. Impervious gloves.

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

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.

# 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state
Appearance
Color
Color
Odor
Liquid
viscous
colorless
unpleasant

Odor threshold No information available

PropertyValuesRemarks • MethodpH10None known

Melting point / freezing point 10.3 °C / 50.5 °F None known 170.8 °C / 339.4 °F Boiling point / boiling range None known Flash point 86 °C / 186.8 °F None known **Evaporation rate** no data available None known Flammability (solid, gas) no data available None known Flammability Limit in Air None known

Upper flammability or explosive 23.5%

limits

Lower flammability or explosive 3%

limits

Vapor pressure0.1None knownVapor density2.1None knownRelative density1.018None knownWater solubilitySoluble in cold waterNone known

Water solubility Soluble in cold wate Soluble in hot water

Calculate in Martin and

Solubility(ies) Soluble in Methanol None known

Soluble in Acetone

Partially soluble in diethyl ether Slightly soluble in Petroleum Ether

Partition coefficient -1.31 None known

Autoignition temperature 410 °C / 770 °F Decomposition temperature

410 °C / 770 °F

None known
None known
No data available
No data available
None known
No me known

Other information

Kinematic viscosity

**Dynamic viscosity** 

Explosive propertiesNo information availableOxidizing propertiesNo information availableSoftening pointNo information available

Molecular weight 61.08 g/mol

VOC Content (%) No information available

Liquid Density

No information available

Bulk density

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. Exposure to air or moisture over prolonged periods. Excessive

heat.

Incompatible materials Acids. Bases. Oxidizing agent.

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. Corrosive by inhalation.

(based on components). Inhalation of corrosive fumes/gases may cause coughing, choking, headache, dizziness, and weakness for several hours. Pulmonary edema may occur with tightness in the chest, shortness of breath, bluish skin, decreased blood pressure, and increased heart rate. Inhaled corrosive substances can lead to a toxic edema of the lungs.

Pulmonary edema can be fatal. Harmful by inhalation.

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

damage. (based on components). Corrosive to the eyes and may cause severe damage

including blindness. May cause irreversible damage to eyes.

**Skin contact** Specific test data for the substance or mixture is not available. Corrosive. (based on

components). Causes burns. May cause sensitization by skin contact. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. May be

absorbed through the skin in harmful amounts. Harmful in contact with skin.

**Ingestion** Specific test data for the substance or mixture is not available. Causes burns. (based on

components). Ingestion causes burns of the upper digestive and respiratory tracts. May cause severe burning pain in the mouth and stomach with vomiting and diarrhea of dark blood. Blood pressure may decrease. Brownish or yellowish stains may be seen around the mouth. Swelling of the throat may cause shortness of breath and choking. May cause lung

damage if swallowed. May be fatal if swallowed and enters airways.

Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** Redness. Burning. May cause blindness. Coughing and/ or wheezing. Itching. Rashes.

Hives.

**Acute toxicity** 

**Numerical measures of toxicity** 

#### Unknown acute toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Ethanolamine	= 1720 mg/kg (Rat)	= 1 mL/kg (Rabbit) = 1000	-
141-43-5		mg/kg(Rabbit)	

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

**Skin corrosion/irritation** Classification based on data available for ingredients. Causes burns.

Serious eye damage/eye irritation Classification based on data available for ingredients. Risk of serious damage to eyes.

Causes burns.

Respiratory or skin sensitization

Germ cell mutagenicity

May cause sensitization by skin contact.

No information available.

Reproductive toxicity No information available.

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

Target organ effects

respiratory system, Eyes, Skin, central nervous system.

**Aspiration hazard** No information available.

Other adverse effects No information available.

Interactive effects No information available.

# 12. Ecological information

**Ecotoxicity** Harmful to aquatic life with long lasting effects.

Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
			microorganisms	
Ethanolamine	EC50: =15mg/L (72h,	LC50: 114 - 196mg/L	-	EC50: =65mg/L (48h,
141-43-5	Desmodesmus	(96h, Oncorhynchus		Daphnia magna)
	subspicatus)	mykiss) LC50: 300 -		_
		1000mg/L (96h, Lepomis		
		macrochirus) LC50:		
		=227mg/L (96h,		
		Pimephales promelas)		
		LC50: =3684mg/L (96h,		
		Brachydanio rerio) LC50:		
		>200mg/L (96h,		
		Oncorhynchus mykiss)		

Persistence and degradability Bioaccumulation

No information available. Inherently biodegradable.

**Component Information** 

Chemical name	Partition coefficient
Ethanolamine	-1.91
141-43-5	

Other adverse effects No information available.

# 13. Disposal considerations

#### Waste treatment methods

products

Waste from residues/unused

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

**Contaminated packaging** Do not reuse empty containers.

# 14. Transport information

DOT

UN/ID no UN2491
Proper Shipping Name: Ethanolamine

Hazard class 8
Packing group: |||

Special Provisions IB3, T4, TP1

Marine Pollutant

Description:

Severe Marine Pollutant
UN2491, Ethanolamine, 8, III

**Emergency Response Guide** 153

Number

TDG

UN-No: UN2491
Proper Shipping Name: Ethanolamine

Hazard class 8
Packing Group:

**Description:** UN2491, Ethanolamine, 8, III

<u>MEX</u>

UN-No UN2491
Proper Shipping Name Ethanolamine

Hazard class 8
Special Provisions 223
Packing Group III

**Description** UN2491, Ethanolamine, 8, III

ICAO (air)

UN-No: UN2491
Proper Shipping Name: Ethanolamine

Hazard class 8
Packing Group: III
Special Provisions A3

**Description:** UN2491, Ethanolamine, 8, III

<u>IATA</u>

UN number UN2491
Proper Shipping Name: Ethanolamine

Transport hazard class(es) 8
Packing group III

**Description:** UN2491, Ethanolamine, 8, III

<u>IMDG</u>

UN number UN2491
Proper shipping name Ethanolamine

Transport hazard class(es) 8
Packing group III
EmS-No F-A, S-B
Special Provisions 223
Marine pollutant NP1

**Description** UN2491, Ethanolamine, 8, III

RID

UN number UN2491
Proper Shipping Name: Ethanolamine

Transport hazard class(es) 8
Packing group III
Classification code C7

**Description:** UN2491, Ethanolamine, 8, III

Labels 8

ADR

UN number 2491

Proper Shipping Name: Ethanolamine

Transport hazard class(es) 8
Packing group III
Classification code C7

Tunnel restriction code (E)

**Description:** 2491, Ethanolamine, 8, III, (E)

Labels 8

**ADN** 

UN/ID No UN2491
Proper shipping name Ethanolamine

Transport hazard class(es) 8
Packing Group III
Classification code C7

**Description** UN2491, Ethanolamine, 8, III

Hazard label(s) 8
Limited quantity (LQ) 5 L
Equipment Requirements PP, EP

# 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 PICCS 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 does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

## 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, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

#### **US State Regulations**

#### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

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

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

#### U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

# 16. Other information

NFPA

Health hazards 3 Flammability 2 Instability 0

Physical and chemical properties -

**HMIS** 

Health hazards 3 Flammability 2 Physical hazards 0 Personal protection X

# 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 (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 Revision Note**09-September-2020
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
M1322	Monoethanolamine, 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

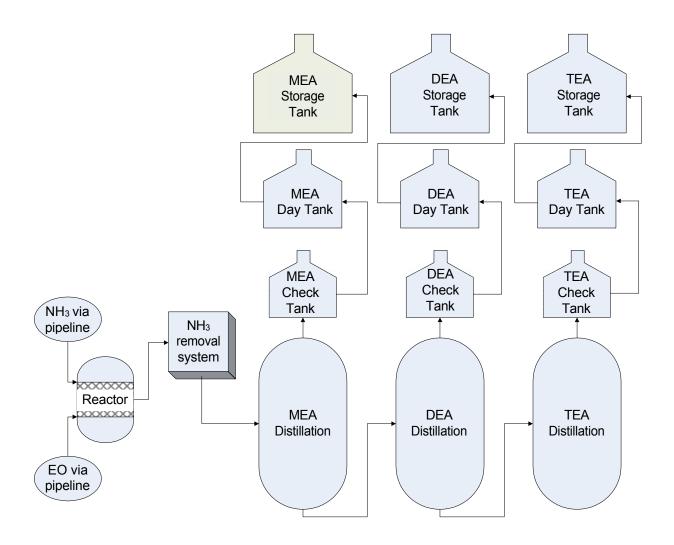
**Quality Assurance Specialist** 

Order Clony



# **Manufacturing Process Flowchart**

# Monoethanolamine, NF - M1322



# Spectrum Chemical Mfg Corp

**Corporate Headquarters:** 769 Jersey Ave.

New Brunswick, NJ 08901

14422 S. San Pedro St. Gardena, CA 90248

West Coast Facility:

732.214.1300 310.516.8000



# M1322, Monoethanolamine, 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

# **EU Fragrance Allergen Statement**

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

#### **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 was tested on laboratory animals in year 2004.

# **Organic Compliance Statement**

The above mentioned catalog item has not been produced using GMOs, irradiation or sewage sludge.

# **Shelf Life Statement**

The above mentioned catalog item is typically assigned a shelf life of 18 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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives



RE: Elemental Impurities - Monoethanolamine, NF (Cat# M1322)

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 - Monoethanolamine, NF (Cat # M1322)

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 the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

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.

# DANGER



 Causes severe skin burns and eye damage
 Harmful if swallowed in contact with skin or if inhaled • May cause an allergic skin reaction • Combustible liquid

 Keep away from flames and hot surfaces • No smoking •
Do not eat, drink or smoke when using this product • Wear protective gloves, protective clothing, eye protection, face protection • Avoid breathing mist or vapors • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling • Contaminated ¬ work clothing must not be allowed out of the workplace.

➤ FIRST AID: Immediately call a POISON CENTER or

¬ physician. IF IN EYES: Rinse cautiously with water for

□ physician. IF IN EYES: Rinse cautiously with water for

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□ physician. II IN EYES: Rinse cautiously with water for the physician water for the phys several minutes. Remove contact lenses, if present
 and easy to do. Continue rinsing. IF ON SKIN: Take off immediately all contaminated clothing. Rinse skin with water. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth. DO NOT induce vomiting. IN CASE OF FIRE: Use dry chemical, water spray,

alcohol-resistant foam or CO, to extinguish **KEEP FROM CHILDREN** 

# SIZ SY M1322 Monoethanolamine

(2-Aminoethanol; Ethanolamine)

NF

CAS 141-43-5

CAUTION: For manufacturing, processing or repacking.

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

DOT: UN2491, Ethanolamine, 8, PG III

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

 $C_2H_7NO$ 

Assay (by Wt )

F.W. 61.08

98 0-100 5%

7100dy (by VVI.)	0.0 /0
Specific Gravity @ 25°C1.013-	1.016
Distilling Range (95%) 167°-1	73°C
MAXIMUM LIMITS	
Residue on Ignition	0.1%
Elemental ImpuritiesAs rep	orted
Residual SolventsTo pas	s test

HYGROSCOPIC: Keep tightly closed; Store at 15-30°C.

Lot No. XQ#### W 6/H1GHS

# Spectrum Chemical Mfg Corp

Corporate Headquarters:

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