

# **Scientific Documentation**

## Trolamine, 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 Trolamine, NF (TR143)**

Item Number	TR143
Item	Trolamine, NF
CAS Number	102-71-6
Molecular Formula	$C_6H_{15}NO_3$
Molecular Weight	149.19
MDL Number	
Synonyms	Triethanolamine; 2,2,2-Nitrilotriethanol; TEA

Test	Specification		
	Min	Max	
APPEARANCE			
ASSAY TOTAL ALKANOLAMINES, AS N(CH <sub>2</sub> CH <sub>2</sub> OH)	99.0	107.4 %	
SPECIFIC GRAVITY @ 25°C	1.120	1.128	
REFRACTIVE INDEX @ 20°C	1.481	1.486	
WATER DETERMINATION		0.5 %	
RESIDUE ON IGNITION		0.05 %	
ELEMENTAL IMPURITIES:			
CADMIUM (Cd)	AS REPORTED		
LEAD (Pb)	AS REPORTED		
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE		
IDENTIFICATION B (1)	DEEP BLUE COLOR PRODUCED		
IDENTIFICATION B (2)	BLUE COLOR REMAINS		
IDENTIFICATION (C)	CARMINE RED COLOR PRODUCED		
EXPIRATION DATE			
DATE OF MANUFACTURE			
MONOGRAPH EDITION			
RESIDUAL SOLVENTS	AS REPORTED		

Corporate Headquarters: West Coast Facility:

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	TR143	Lot Number	1NC0131
Item	Trolamine, NF	CAS Number	102-71-6
Molecular Formula	$C_6H_{15}NO_3$	Molecular Weight	149.19

TT-CT	SPECIFICATION		250.47	
TEST	MIN	MAX	RESULT	
APPEARANCE			CLEAR COLORLESS LIQUID	
ASSAY TOTAL ALKANOLAMINES, AS N(CH $_2$ CH $_2$ OH) $_3$	99.0	107.4 %	99.5 %	
SPECIFIC GRAVITY @ 25°C	1.120	1.128	1.123	
REFRACTIVE INDEX @ 20°C	1.481	1.486	1.484	
WATER DETERMINATION		0.5 %	0.1 %	
RESIDUE ON IGNITION		0.05 %	0.02 %	
ELEMENTAL IMPURITIES:				
CADMIUM (Cd)	AS REPORTED		0.2 μg/g	
LEAD (Pb)	AS REPORTED		0.5 μg/g	
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE	
IDENTIFICATION B (1)	DEEP BLUE COLOR PRODUCED		DEEP BLUE COLOR PRODUCED	
IDENTIFICATION B (2)	BLUE COLOR REMAINS		BLUE COLOR REMAINS	
IDENTIFICATION (C)	CARMINE RED COLOR PRODUCED		CARMINE RED COLOR PRODUCED	
EXPIRATION DATE			30-APR-2025	
DATE OF MANUFACTURE			09-OCT-2023	
MONOGRAPH EDITION			(USP-NF) 2023	
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENT PRESENT	

Certificate of Analysis Results Entered By:

AMENDEZ Ana Mendez 23-APR-24 11:43:07

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



Certificate of Analysis Results Approved By:

HBERMUDEZ Hernan Bermudez 23-APR-24 12:08:57

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.





Revision date 19-April-2024 Revision Number 3

#### 1. Identification

**Product identifier** 

Product Name TROLAMINE, NF

Other means of identification

Product Code(s) TR143

Synonyms Trolamine

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

Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Skin sensitization	Category 1A

#### Hazards not otherwise classified (HNOC)

Not applicable

#### Label elements

#### Warning

#### Hazard statements

Causes skin irritation Causes serious eye irritation May cause an allergic skin reaction



Appearance viscous Physical state Liquid Odor Slight Ammonia

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

Wash face, hands and any exposed skin thoroughly after handling

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

Contaminated work clothing must not be allowed out of the workplace

Wear protective gloves/eye protection/face protection

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

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 IF ON SKIN: Wash with plenty of water and soap Take off contaminated clothing and wash it before reuse

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

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

Dispose of contents/container to an approved waste disposal plant

#### Other information

No information available.

#### 3. Composition/information on ingredients

#### Substance

Not applicable.

#### <u>Mixture</u>

Synonyms Trolamine.

Chemical name	CAS No	Weight-%
Triethanolamine	102-71-6	99 - 100
Diethanolamine	111-42-2	0.1 - 0.9

#### 4. First-aid measures

#### Description of first aid measures

**General advice** Show this safety data sheet to the doctor in attendance.

**Inhalation** Remove to fresh air. Get medical attention immediately if symptoms occur.

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

eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists. Do not rub affected area.

**Skin contact**May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a

physician. Wash off immediately with soap and plenty of water for at least 15 minutes.

**Ingestion** Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth

to an unconscious person. Do NOT induce vomiting. Call a physician.

Self-protection of the first aider Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Symptoms Itching. Rashes. Hives. May cause redness and tearing of the eyes. Burning sensation.

Indication of any immediate medical attention and special treatment needed

Note to physicians May cause sensitization in susceptible persons. Treat symptomatically.

#### 5. Fire-fighting measures

surrounding environment.

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

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

Hazardous combustion products Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NOx). Ammonia. Hydrogen cyanide.

**Explosion data** 

Sensitivity to mechanical impact none.

Sensitivity to static discharge none.

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

Personal precautions Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal

protective equipment as required. Evacuate personnel to safe areas. Keep people away

from and upwind of spill/leak.

**Other information** Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Pick up and transfer to properly labeled containers.

#### 7. Handling and storage

#### Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with

skin, eyes or clothing. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. 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

locked up. Keep out of the reach of children.

#### 8. Exposure controls/personal protection

#### Control parameters

**Exposure Limits** The following ingredients are the only ingredients of the product above the cut-off level (or

level that contributes to the hazard classification of the mixture) which have an exposure

limit applicable in the region for which this safety data sheet is intended or other

recommended limit. At this time, the other relevant constituents have no known exposure

limits from the sources listed here.

#### **Appropriate engineering controls**

Engineering controls Showers

Eyewash stations Ventilation systems.

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

**Eye/face protection** Wear safety glasses with side shields (or goggles).

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

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

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 Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this

product. Avoid contact with skin, eyes or clothing.

#### 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Liquid Appearance viscous

ColorColorless light yellowOdorSlight Ammonia

Odor threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

pHno data availableNone knownMelting point / freezing point17.9 - 21 °C / 64.2 - 69.8 °FNone knownBoiling point / boiling range335 °C / 635 °FNone knownFlash point17.9 - 190.5 °C / 354.2 - 374.9None known

°F

Evaporation rateno data availableNone knownFlammability (solid, gas)no data availableNone knownFlammability Limit in AirNone known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Vapor pressureNo data availableNone knownVapor density5.14None knownRelative density1.120 - 1.128None knownWater solubilityCompletely soluble in waterNone known

Soluble in Chloroform None known Solubility(ies)

Soluble in Benzene

Slightly soluble in Petroleum Ether

Soluble in Ether

Slightly soluble in Carbon Tetrachloride

-2.53 None known **Partition coefficient Autoignition temperature** 324 °C / 615.2 °F None known **Decomposition temperature** None known

None known

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

Other information

No information available **Explosive properties Oxidizing properties** No information available Softening point No information available No information available Molecular weight **VOC Content (%)** No information available No information available **Liquid Density Bulk density** No information available

#### 10. Stability and reactivity

No information available. Reactivity

Stable under normal conditions. Chemical stability

None under normal processing. Possibility of hazardous reactions

Conditions to avoid None known based on information supplied.

Strong acids. Strong bases. Strong oxidizing agents. Incompatible materials

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.

Specific test data for the substance or mixture is not available. Irritating to eyes. (based on Eve contact

components). Causes serious eye irritation.

May cause sensitization by skin contact. Specific test data for the substance or mixture is Skin contact

not available. Repeated or prolonged skin contact may cause allergic reactions with

susceptible persons. (based on components). Causes skin irritation.

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

gastrointestinal irritation, nausea, vomiting and diarrhea.

Symptoms related to the physical, chemical and toxicological characteristics

Itching. Rashes. Hives. Redness. May cause redness and tearing of the eyes. **Symptoms** 

Acute toxicity

**Numerical measures of toxicity** 

**Component Information** 

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Triethanolamine 102-71-6	= 4190 mg/kg (Rat)	> 20000 mg/kg (Rabbit)	-
Diethanolamine 111-42-2	= 780 mg/kg (Rat)	= 11.9 mL/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. Irritating to skin.

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

**Respiratory or skin sensitization** May cause sensitization by skin contact.

Germ cell mutagenicity No information available.

**Carcinogenicity** No information available.

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

Chemical name	ACGIH	IARC	NTP	OSHA
Triethanolamine	-	Group 3 -Monograph 77	-	-
102-71-6		[2000]		
Diethanolamine	-	Group 2B - Monograph	-	-
111-42-2		101 [2013]		
		Monograph 77 [2000]		

#### Legend

#### IARC (International Agency for Research on Cancer)

Group 1 - Carcinogenic to Humans

Group 2B - Possibly Carcinogenic to Humans

Group 3 - Not Classifiable as to Carcinogenicity in Humans

Reproductive toxicity No information available.

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

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

**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	
Triethanolamine 102-71-6	EC50: =169mg/L (96h, Desmodesmus subspicatus) EC50: =216mg/L (72h, Desmodesmus	LC50: 10600 - 13000mg/L (96h, Pimephales promelas) LC50: 450 - 1000mg/L (96h, Lepomis macrochirus) LC50:		EC50: =1386mg/L (24h, Daphnia magna)
	subspicatus)	>1000mg/L (96h, Pimephales promelas)		
Diethanolamine 111-42-2	EC50: 2.1 - 2.3mg/L (96h, Pseudokirchneriella subcapitata) EC50: =7.8mg/L (72h, Desmodesmus subspicatus)	LC50: 1200 - 1580mg/L (96h, Pimephales promelas) LC50: 4460 - 4980mg/L (96h, Pimephales promelas) LC50: 600 - 1000mg/L	-	EC50: =55mg/L (48h, Daphnia magna)

	(96h, Lepomis	
	macrochirus)	
	macrocimas	

Persistence and degradability

No information available.

Bioaccumulation

Inherently biodegradable.

**Component Information** 

Chemical name	Partition coefficient
Triethanolamine	-2.53
102-71-6	
Diethanolamine	-2.18
111-42-2	

Other adverse effects No information available.

#### 13. Disposal considerations

#### Waste treatment methods

Waste from residues/unused

products

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** not regulated

TDG not regulated

MEX not regulated

ICAO (air) not regulated

<u>IATA</u> not regulated

**IMDG** not regulated

RID not regulated

ADR not regulated

<u>ADN</u> not regulated

#### 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 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 %
Diethanolamine - 111-42-2	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
Diethanolamine	100 lb final RQ	-
111-42-2	45.4 kg final RQ	

#### **US State Regulations**

#### **California Proposition 65**

This product contains the following Proposition 65 chemicals:.

Chemical name	California Proposition 65
Diethanolamine - 111-42-2	carcinogen

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

Chemical name	New Jersey	Massachusetts	Pennsylvania
Triethanolamine 102-71-6	4094	Present	Present
Diethanolamine 111-42-2	0686	Present	Environmental hazard

#### U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

#### 16. Other information

#### NFPA

Health hazards 2

Flammability 1 Instability 0

Physical and chemical properties -

**HMIS** 

Health hazards 2 \*
Flammability 1
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 (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 19-April-2024

**Revision Note**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
TR143	Trolamine, 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 qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez

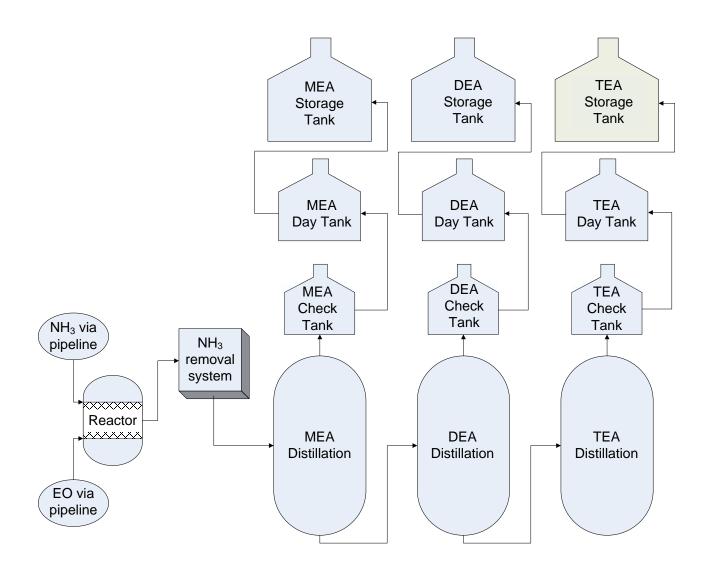
**Quality Assurance Specialist** 

Order Clony



### **Manufacturing Process Flowchart**

### **Trolamine, NF - TR143**



#### Spectrum Chemical Mfg Corp

Corporate Headquarters: 769 Jersey Ave.

New Brunswick, NJ 08901

732.214.1300

West Coast Facility:

14422 S. San Pedro St. Gardena, CA 90248

310.516.8000



### TR143, Trolamine, 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 item does not use or add melamine to the manufacturing process and is considered melamine-free.

#### **Nitrosamine Statement**

Based on knowledge of the manufacturing process, the above mentioned catalog item meets the requirements of the European Cosmetics Regulation EC No. 1223/2009. The maximum Diethanolamine content is < 0.5% and the maximum NDELA is < 50 ppb. The packaging for this product is nitrate-free.



#### **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 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:

- Antibiotics
- Bisphenol A (BPA)
- Parabens

- Pesticides
- Phthalates
- Preservatives



#### RE: Elemental Impurities – Trolamine, NF (Cat# TR143)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	< 0.2 ppm
Lead	Pb	1	< 0.5 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not 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 – Trolamine, NF (Cat# TR143)**

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>.

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



#### **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.

#### WARNING

the workplace.



 Causes serious eye irritation
 Causes skin irritation
 May cause an allergic skin reaction.

 Wear protective gloves, eye protection, face protection • Avoid breathing mist or vapors
 Wash face, hands and any exposed skin thoroughly after handling • Contaminated work clothing must not be allowed out of

FIRST AID: 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 attention. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. If skin irritation or rash occurs: Get medical attention

**KEEP FROM CHILDREN** 

# TR143 SIZ SY Trolamine

(2,2´,2´´-Nitrilotriethanol; Triethanolamine)

N.F.

CAS 102-71-6

**CAUTION:** For manufacturing, processing or repacking.

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

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

 $C_6H_{15}NO_3$ 

F.W. 149.19

Also contains mono- and diethanolamine.

Assay [Total Alkanolamines, as N(C	G <sub>2</sub> H <sub>4</sub> OH) <sub>3</sub> ]	
	99.0-107.4%	
Specific Gravity @ 25°C	1.120-1.128	
Refractive Index @ 20°C	1.481-1.486	
MAXIMUM LIMITS		
Water Determination	0.5%	
Residue on Ignition	0.05%	
Elemental Impurities		
Residual Solvents	To pass test	

LIGHT SENSITIVE: Keep tightly closed in light-resistant containers.

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

G 12/G11GHS ? Lot No. XQ####

#### Spectrum Chemical Mfg Corp

Corporate Headquarters:

New Brunswick, NJ 08901

West Coast Facility:

769 Jersey Ave.

14422 S. San Pedro St. Gardena, CA 90248

732.214.1300

310.516.8000