



Scientific Documentation

T9700, Tris(hydroxymethyl)aminomethane,
USP, EP, BP, bioCERTIFIED™

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

Ver4.06 4.May.2021

T9700, Tris(hydroxymethyl)aminomethane, USP, EP, BP, bioCERTIFIED™

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spectrum®

Item Number	T9700
Item	Tris(hydroxymethyl)aminomethane, USP, EP, BP, bioCERTIFIED™
CAS Number	77-86-1
Molecular Formula	C ₄ H ₁₁ NO ₃
Molecular Weight	121.14
MDL Number	
Synonyms	TRIS Base ; TRIS ; Trismat ; Trometamol ; Tromethamine

Test	Specification	
	Min	Max
APPEARANCE	White or almost white, crystalline powder or colorless crystals	
ASSAY BY TITRATION (DRIED BASIS, USP, EP)	99.0	100.5 %
MELTING RANGE (USP; ID B, EP)	168°	172°C
APPEARANCE OF SOLUTION (EP)	CLEAR AND COLORLESS	
pH OF A 5% SOLUTION @ 25°C (USP, EP)	10.0	11.5
APHA COLOR, 20% AQUEOUS SOLUTION		20
ULTRAVIOLET ABSORBANCE (10% Aqueous Solution vs. water):		
@ 430 nm		0.004
@ 280 nm		0.02
@ 260 nm		0.03
ULTRAVIOLET ABSORBANCE (40% Aqueous Solution vs. water):		
@ 290 nm		0.2
LOSS ON DRYING (USP, EP)		0.5 %
RESIDUE ON IGNITION (USP, EP)		0.1 %
CHLORIDES (EP)		100 ppm
IRON (EP)		5 ppm
WATER		0.2 %
WATER INSOLUBLE MATTER		0.005 %
RELATED SUBSTANCES (EP)	TO PASS TEST	
MICROBIAL LIMITS:		
BIOBURDEN		100 CFU/g
ENDOTOXIN		0.03 EU/mg
IDENTIFICATION A (USP; ID C EP)	TO PASS TEST	
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION B (USP)	TO PASS TEST	
IDENTIFICATION C (USP)	TO PASS TEST	
IDENTIFICATION D (EP)	TO PASS TEST	
EXPIRATION DATE		
MANUFACTURE DATE		
RESIDUAL SOLVENTS	TO PASS TEST	

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

Item Number	T9700	Lot Number	4JD0018
Item	Tris(hydroxymethyl)aminomethane, USP, EP, BP bioCERTIFIED™		
CAS Number	77-86-1		
Molecular Formula	C ₄ H ₁₁ NO ₃	Molecular Weight	121.14

Test	Specification		Result
	min	max	
ASSAY BY TITRATION (DRIED BASIS, USP, EP)	99.0	100.5 %	100.1 %
MELTING RANGE (USP; ID B, EP)	168°	172°C	168°C - 171°C
APPEARANCE OF SOLUTION (EP)	CLEAR AND COLORLESS		CLEAR AND COLORLESS
pH OF A 5% SOLUTION @ 25°C (USP, EP)	10.0	11.5	10.6
APHA COLOR, 20% AQUEOUS SOLUTION		20	<20
ULTRAVIOLET ABSORBANCE (10% Aqueous Solution vs. water):			.
@ 430 nm		0.004	0.0008
@ 280 nm		0.02	0.0116
@ 260 nm		0.03	0.0131
ULTRAVIOLET ABSORBANCE (40% Aqueous Solution vs. water):			.
@ 290 nm		0.2	0.0343
LOSS ON DRYING (USP, EP)		0.5 %	0.48 %
RESIDUE ON IGNITION (USP, EP)		0.1 %	0.0 %
CHLORIDES (EP)		100 ppm	<100 ppm
IRON (EP)		5 ppm	<5 ppm
WATER		0.2 %	0.05 %
WATER INSOLUBLE MATTER		0.005 %	0.002 %
RELATED SUBSTANCES (EP)	TO PASS TEST		PASSES TEST
MICROBIAL LIMITS:			.
BIOBURDEN		100 CFU/g	<100 CFU/g
ENDOTOXIN		0.03 EU/mg	<0.03 EU/mg
IDENTIFICATION A (USP; ID C EP)	TO PASS TEST		PASSES TEST
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
IDENTIFICATION B (USP)	TO PASS TEST		PASSES TEST
IDENTIFICATION C (USP)	TO PASS TEST		PASSES TEST
IDENTIFICATION D (EP)	TO PASS TEST		PASSES TEST
EXPIRATION DATE			26-JAN-2022
MANUFACTURE DATE			27-JAN-2020
APPEARANCE			COLORLESS CRYSTALS
RESIDUAL SOLVENTS	TO PASS TEST		PASSES TEST
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm

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



Certificate of Analysis Results Certified by:

A thick, black, handwritten signature that appears to read "Himanshu Patel". The signature is written in a cursive style with several horizontal strokes across the middle.

Himanshu Patel
Quality Control Manager
Spectrum Chemicals & Laboratory Products

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.

SAFETY DATA SHEET

spectrum®



Revision date 08-April-2020

Revision Number 1

1. Identification

Product identifier

Product Name Tris(hydroxymethyl)aminomethane, USP, EP, BP, bioCERTIFIED™

Other means of identification

Product Code(s) T9700

Synonyms Tromethamine
Trometamol
TRIS

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

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

Causes skin irritation
Causes serious eye irritation



Appearance crystalline powder

Physical state Solid

Odor Odorless

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling

Wear protective gloves/eye protection/face protection

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

If skin irritation occurs: Get medical advice/attention

Take off contaminated clothing and wash it before reuse

Other information

No information available.

3. Composition/information on ingredients

Substance

Synonyms

Tromethamine.

Trometamol.

TRIS.

Chemical name	CAS No	Weight-%	Trade secret
Tromethamine	77-86-1	100	*

*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.

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

Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

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

May cause redness and tearing of the eyes. Burning sensation.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. Fire-fighting measures

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the 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	No information available.
Hazardous combustion products	Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NOx).
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.
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. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.
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Conditions for safe storage, including any incompatibilities

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

Molecular weight	121.14
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	None known based on information supplied.
Incompatible materials	Strong acids. Strong bases. Strong oxidizing agents.
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.
Eye contact	Specific test data for the substance or mixture is not available. Irritating to eyes. (based on components). Causes serious eye irritation.
Skin contact	Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components).
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

Symptoms	Redness. May cause redness and tearing of the eyes.
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Acute toxicity

Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Tromethamine 77-86-1	= 5900 mg/kg (Rat)	-	-

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	No information available.
Germ cell mutagenicity	No information available.
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	The environmental impact of this product has not been fully investigated.
Persistence and degradability	No information available.
Bioaccumulation	Inherently biodegradable.
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

<u>DOT</u>	not regulated
<u>TDG</u>	not regulated
<u>MEX</u>	not regulated
<u>ICAO (air)</u>	not regulated
<u>IATA</u>	not regulated
<u>IMDG</u>	not regulated
<u>RID</u>	not regulated
<u>ADR</u>	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 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 2

Flammability 0

Instability 0

Physical and chemical properties -

HMIS

Health hazards 2

Flammability 0

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 08-April-2020

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
T9700	Tris(hydroxymethyl)aminomethane, USP, EP, BP, bioCERTIFIED™

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

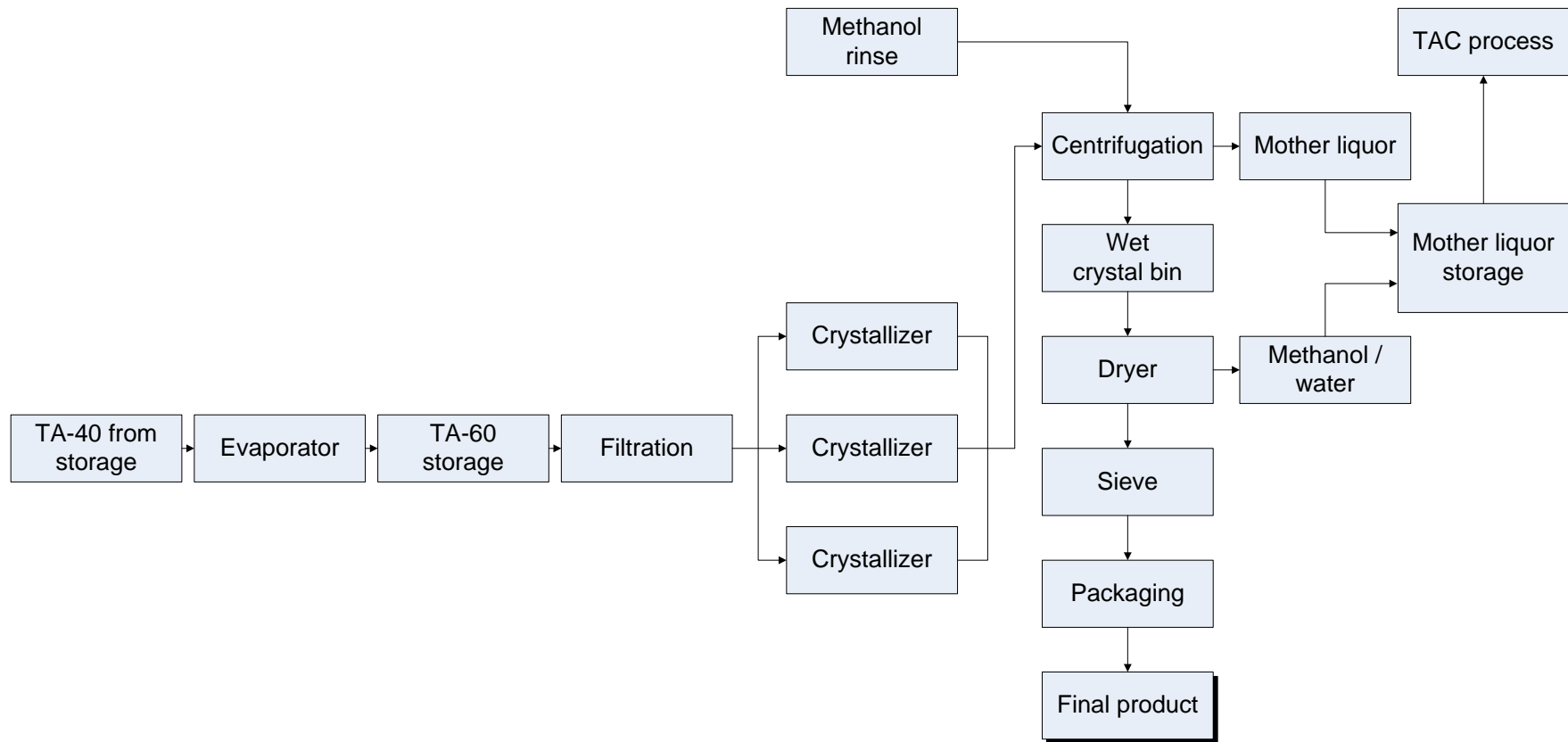
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Tris(hydroxymethyl)aminomethane, USP, EP, BP, bioCERTIFIED™ - T9700



Spectrum Chemical Mfg Corp

Corporate Headquarters:
769 Jersey Ave.
New Brunswick, NJ 08901

West Coast Facility:
14422 S. San Pedro St.
Gardena, CA 90248



Tris(hydroxymethyl)aminomethane, USP, EP, BP, bioCERTIFIED™ - T9700

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 known or suspected to be present in this material at an maximum expected concentration of <50 ppb.

Animal Testing Statement

The above mentioned catalog item has been tested on animals. The last date of testing was Dec 31, 2002 for non-cosmetic uses, to meet the requirements of REACH compliance in Europe.

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 36 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 - Tris(hydroxymethyl)aminomethane, USP, EP, BP, bioCERTIFIED™ (Cat# T9700)

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
Cobalt	Co	2A	Not detected
Vanadium	V	2A	Not detected
Nickel	Ni	2A	< 2.0 ppm
Molybdenum	Mo	3	Not detected
Copper	Cu	3	Not detected
Chromium	Cr	3	Not detected

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 TechServices@spectrumchemical.com.

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 - Tris(hydroxymethyl)aminomethane, USP, EP, BP, bioCERTIFIED™ (Cat# T9700)

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 solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Methanol	2	< 3000 ppm

No Class 1, Class 3 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 TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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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.

WARNING
 • Causes serious eye irritation • Causes skin irritation.
 • Wear protective gloves, eye protection, face protection • Wash face, hands and any exposed skin thoroughly after handling.
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 occurs: Get medical attention.
KEEP FROM CHILDREN
WARNING: Cancer and Reproductive Harm - www.P65Warnings.ca.gov

Tris(hydroxymethyl)-aminomethane
 (Trometamol; Tromethamine)
 USP, EP, BP,
 bioCERTIFIED™
 CAS 77-86-1

CAUTION: For manufacturing, processing or repacking. Further processing and testing required for use in parenteral applications. Read and understand the label and Safety Data Sheet (SDS) prior to use.

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

Technical Specifications Panel:
 $C_4H_{11}NO_3$ F.W. 121.14
 Not sterile.
 Appearance White or almost white, crystalline powder or colorless crystals
 Identification A (USP; ID C, EP) To pass test
 Identification B (USP) To pass test
 Identification C (USP) To pass test
 Identification D (EP) To pass test
 Appearance of Solution (EP) Clear and colorless
 Assay by Titration (Dried Basis, USP, EP) 99.0-100.5%
 Melting Range (USP; ID B, EP) 168-172°C
 pH of a 5% Solution @ 25°C (USP, EP) 10.0-11.5

MAXIMUM LIMITS
 APHA Color, 20% Aqueous Solution 20
 Ultraviolet Absorbance (10% Aqueous Solution vs. Water):
 λ.(nm) 430 280 260
 Limit 0.004 0.02
 Ultraviolet Absorbance (40% Aqueous Solution vs. Water):
 λ.(nm) 290
 Limit 0.2
 Loss on Drying (USP, EP) 0.5%
 Residue on Ignition (USP, EP) 0.1%
 Chlorides (EP) 100 ppm
 Iron (EP) 5 ppm
 Water 0.2%
 Water Insoluble Matter 0.005%
 Related Substances (EP) To pass test
 Endotoxin 0.03 EU/mg
 Bioburden 100 CFU/g
 Elemental Impurities As reported
 Residual Solvents To pass test

HYGROSCOPIC: Keep tightly closed.
 G 5/K4GHS A Lot No. 062233

SPECTRUM CHEMICAL MFG. CORP. Gardena, CA 90248 • New Brunswick, NJ 08901

- A** Bar Code
- B** GHS Hazard Pictograms
- C** Warning, Safety Data and Precautionary Information
- D** Product Catalog Number
- E** Item Name, Form, Grade
- F** Size/Quantity
- G** Chemical Abstracts Service (CAS) Registry Number
- H** Caution Information
- I** DOT Shipping Information
- J** Toll-Free 24-Hour Chemical Emergency Telephone Number
- K** Empirical Formula, Formula Weight and Technical Specifications Panel
- L** Expiration Information
- M** Lot Number
- N** Kosher Certified by Kosher Supervision of America (KSA).
- O** Storage Color Band
- P** Halal Certified by IFANCA
- Q** bioCertified

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

- **YELLOW:** Oxidizer
- **RED:** Flammable
- **GREEN:** General Storage
- **BLUE:** Health Hazard
- WHITE:** Corrosive

Spectrum Chemical Mfg Corp

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 732.214.1300

West Coast Facility:

14422 S. San Pedro St.
 Gardena, CA 90248
 310.516.8000



RE: Lot Numbering System

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

Example: ZI0928 = The 928th material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

- 1 = Gardena, CA Facility
- 2 = New Brunswick, NJ Facility
- 3 = China Facility
- 4 = Pharmacy, NJ Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

Example: 2AA0706 = The 706th material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at quality_assurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Oralia Chavez,
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