

# Scientific Documentation

## **Tris(hydroxymethyl)aminomethane, USP, EP, BP, bioCERTIFIED (TM)**

Not appropriate for regulatory submission.

Please visit [www.spectrumchemical.com](http://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 Tris(hydroxymethyl)aminomethane, USP, EP, BP, bioCERTIFIED (TM) (T9700)

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

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	168°	172°C
APHA COLOR, 20% AQUEOUS SOLUTION		20
APPEARANCE OF SOLUTION (EP)	CLEAR AND COLORLESS	
pH OF A 5% SOLUTION @ 25°C (USP, EP)	10.0	11.5
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

Test	Specification	
	Min	Max
IRON (EP)		5 ppm
WATER		0.2 %
WATER INSOLUBLE MATTER		0.005 %
RELATED SUBSTANCES ( EP )		1.0 %
MICROBIAL LIMITS:		
BIOBURDEN		100 CFU/g
ENDOTOXIN		0.03 EU/mg
DNase	NOT DETECTED	
RNase	NOT DETECTED	
PROTEASE	NOT DETECTED	
ELEMENTAL IMPURITIES:		
NICKEL (Ni)	AS REPORTED	
IDENTIFICATION (A) USP	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B) USP	YELLOW COLOR PRODUCED	
IDENTIFICATION (C) USP	LIGHT YELLOW TO ORANGE	
IDENTIFICATION : A (EP/BP)	STRONGLY ALKALINE	
IDENTIFICATION : B (EP/BP)	168°C	174°C
IDENTIFICATION : C (EP/BP)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION D (EP/BP)	SAMPLE CORRESPONDS TO STANDARD	
EXPIRATION DATE		
MANUFACTURE DATE		
MONOGRAPH EDITION		
MONOGRAPH EDITION.		
MONOGRAPH EDITION..		
RESIDUAL SOLVENTS	AS REPORTED	
CLASS 2 (SOLVENT) / METHANOL	.	

***Spectrum Chemical Mfg Corp***

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<b>Corporate Headquarters:</b>	<b>West Coast Facility:</b>
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	T9700	Lot Number	4MG0030
Item	Tris(hydroxymethyl)aminomethane, USP, EP, BP, bioCERTIFIED (TM)	CAS Number	77-86-1
Molecular Formula	C <sub>4</sub> H <sub>11</sub> NO <sub>3</sub>	Molecular Weight	121.14

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE	WHITE OR ALMOST WHITE, CRYSTALLINE POWDER OR COLORLESS CRYSTALS		WHITE CRYSTALS
ASSAY BY TITRATION (DRIED BASIS, USP, EP)	99.0	100.5 %	100.0 %
MELTING RANGE	168°	172°C	168.4°--170.8°C
APHA COLOR, 20% AQUEOUS SOLUTION		20	<20
APPEARANCE OF SOLUTION (EP)	CLEAR AND COLORLESS		CLEAR AND COLORLESS
pH OF A 5% SOLUTION @ 25°C (USP, EP)	10.0	11.5	10.9
ULTRAVIOLET ABSORBANCE (10% Aqueous Solution vs. water):			.
@ 430 nm		0.004	0.0017
@ 280 nm		0.02	0.011
@ 260 nm		0.03	0.011
ULTRAVIOLET ABSORBANCE (40% Aqueous Solution vs. water):			.
@ 290 nm		0.2	0.05
LOSS ON DRYING (USP, EP)		0.5 %	0.1 %
RESIDUE ON IGNITION (USP, EP)		0.1 %	0.01 %
CHLORIDES (EP)		100 ppm	<100 ppm
IRON (EP)		5 ppm	<5 ppm

TEST	SPECIFICATION		RESULT
	MIN	MAX	
WATER		0.2 %	0.1 %
WATER INSOLUBLE MATTER		0.005 %	<0.005 %
RELATED SUBSTANCES ( EP )		1.0 %	<1.0 %
MICROBIAL LIMITS:			.
BIOBURDEN		100 CFU/g	<50 CFU/g
ENDOTOXIN		0.03 EU/mg	<0.03 EU/mg
DNase	NOT DETECTED		NOT DETECTED
RNase	NOT DETECTED		NOT DETECTED
PROTEASE	NOT DETECTED		NOT DETECTED
ELEMENTAL IMPURITIES:			COMPLIES WITH STANDARD
NICKEL (Ni)	AS REPORTED		0.42 ppm
IDENTIFICATION (A) USP	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B) USP	YELLOW COLOR PRODUCED		YELLOW COLOR PRODUCED
IDENTIFICATION (C) USP	LIGHT YELLOW TO ORANGE		LIGHT YELLOW TO ORANGE
IDENTIFICATION : A (EP/BP)	STRONGLY ALKALINE		STRONGLY ALKALINE
IDENTIFICATION : B (EP/BP)	168°C	174°C	170.8°C
IDENTIFICATION : C (EP/BP)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION D (EP/BP)	SAMPLE CORRESPONDS TO STANDARD		SAMPLE CORRESPONDS TO STANDARD
EXPIRATION DATE			26-MAR-2026
MANUFACTURE DATE			27-MAR-2023
MONOGRAPH EDITION			USP 2023
MONOGRAPH EDITION.			BP 11
MONOGRAPH EDITION..			BP 2023
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 2 (SOLVENT) / METHANOL	.		<3000 ppm

Certificate of Analysis Results Entered By:

CACEVEDO  
Charmian Acevedo  
15-APR-24 11:05:21

Spectrum Chemical Mfg Corp  
777 Jersey Avenue  
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS  
Allison Williams  
15-APR-24 11:05:53

**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 06-May-2022

Revision Number 3

## 1. Identification

### Product identifier

**Product Name** TRIS(HYDROXYMETHYL)AMINOMETHANE, USP, EP, BP, BIOCERTIFIED(TM)

### 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**

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Large Fire</b>	CAUTION: Use of water spray when fighting fire may be inefficient.
<b>Unsuitable extinguishing media</b>	Do not scatter spilled material with high pressure water streams.
<b>Specific hazards arising from the chemical</b>	No information available.
<b>Hazardous combustion products</b>	Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NOx).
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	none.
<b>Sensitivity to static discharge</b>	none.
<b>Special protective equipment for fire-fighters</b>	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**

<b>Personal precautions</b>	Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required.
<b>Other information</b>	Refer to protective measures listed in Sections 7 and 8.

### **Methods and material for containment and cleaning up**

<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for cleaning up</b>	Pick up and transfer to properly labeled containers.

## **7. Handling and storage**

### **Precautions for safe handling**

<b>Advice on safe handling</b>	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**

<b>Storage Conditions</b>	Hygroscopic. It absorbs moisture from the air. Protect from moisture. 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 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** If splashes are likely to occur, wear safety glasses with side-shields.

**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** Solid  
**Appearance** Crystalline powder  
**Color** White  
**Odor** Odorless  
**Odor threshold** No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>	no data available	None known
<b>Melting point / freezing point</b>	168 - 172 °C / 334.4 - 341.6 °F	None known
<b>Boiling point / boiling range</b>	no data available	None known
<b>Flash point</b>	no data available	None known
<b>Evaporation rate</b>	no data available	None known
<b>Flammability (solid, gas)</b>	no data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Vapor pressure</b>	No data available	None known
<b>Vapor density</b>	no data available	None known
<b>Relative density</b>	1.3	None known
<b>Water solubility</b>	Soluble in water	None known
<b>Solubility(ies)</b>	Soluble in ethylene glycol Soluble in Methanol Slightly soluble in Acetone Insoluble in Carbon tetrachloride	None known
<b>Partition coefficient</b>	-1.56 to -2.31	None known
<b>Autoignition temperature</b>	no data available	None known
<b>Decomposition temperature</b>		None known
<b>Kinematic viscosity</b>	no data available	None known
<b>Dynamic viscosity</b>	No data available	None known

**Other information**

<b>Explosive properties</b>	No information available
<b>Oxidizing properties</b>	No information available
<b>Softening point</b>	No information available
<b>Molecular weight</b>	121.14
<b>VOC Content (%)</b>	No information available
<b>Liquid Density</b>	No information available
<b>Bulk density</b>	No information available

**10. Stability and reactivity**

<b>Reactivity</b>	No information available.
<b>Chemical stability</b>	Stable under recommended storage conditions.
<b>Possibility of hazardous reactions</b>	None under normal processing.
<b>Conditions to avoid</b>	None known based on information supplied.
<b>Incompatible materials</b>	Strong acids. Strong bases. Strong oxidizing agents.
<b>Hazardous decomposition products</b>	None known based on information supplied.

**11. Toxicological information****Information on likely routes of exposure****Product Information**

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<b>Inhalation</b>	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available. Irritating to eyes. (based on components). Causes serious eye irritation.
<b>Skin contact</b>	Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components).
<b>Ingestion</b>	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**

<b>Symptoms</b>	Redness. May cause redness and tearing of the eyes.
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**Acute toxicity****Numerical measures of toxicity****Component Information**

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**

<b>Skin corrosion/irritation</b>	Classification based on data available for ingredients. Irritating to skin.
<b>Serious eye damage/eye irritation</b>	Classification based on data available for ingredients. Causes serious eye irritation.
<b>Respiratory or skin sensitization</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.

<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration hazard</b>	No information available.
<b>Other adverse effects</b>	No information available.
<b>Interactive effects</b>	No information available.

## 12. Ecological information

<b>Ecotoxicity</b>	The environmental impact of this product has not been fully investigated.
<b>Persistence and degradability</b>	No information available.
<b>Bioaccumulation</b>	Inherently biodegradable.
<b>Other adverse effects</b>	No information available.

## 13. Disposal considerations

### Waste treatment methods

<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.

## 14. Transport information

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

## 15. Regulatory information

### International Inventories

<b>TSCA</b>	Complies
<b>DSL/NDSL</b>	Complies

<b>EINECS/ELINCS</b>	Complies
<b>ENCS</b>	This product complies with ENCS:
<b>IECSC</b>	This product complies with China:
<b>KECL</b>	Complies
<b>PICCS</b>	Complies
<b>AICS</b>	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** 06-May-2022  
**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](mailto:qualityassurance@spectrumchemical.com)

Sincerely,

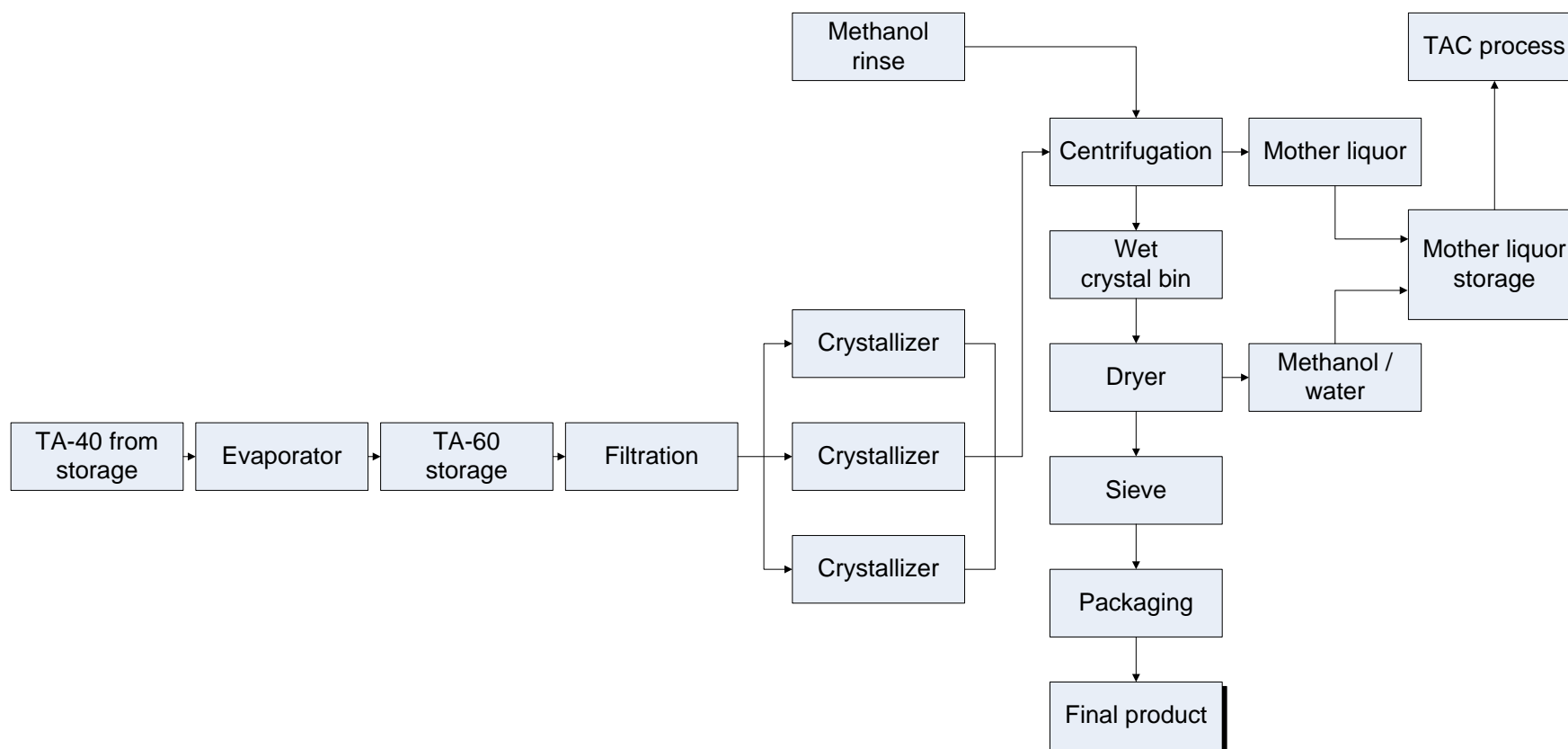
A handwritten signature in black ink, appearing to read "Oralia Chavez".

Oralia Chavez  
Quality Assurance Specialist



## Manufacturing Process Flowchart

### Tris(hydroxymethyl)aminomethane, USP, EP - 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

## **T9700, Tris(hydroxymethyl)aminomethane, USP, EP**

### **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        | • Parabens      |
| • Antibiotics       | • Pesticides    |
| • Bisphenol A (BPA) | • Phthalates    |
| • CMR Substances    | • 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](mailto: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](mailto:TechServices@spectrumchemical.com).

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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.

**Exp. Date: 03-31-2025**

**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](http://www.P65Warnings.ca.gov)

**spectrum®**  
CHEMICAL MFG CORP

**T9700** **2.5 KG**

**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](http://www.SpectrumChemical.com)

**C<sub>4</sub>H<sub>11</sub>NO<sub>3</sub>** **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	0.03

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**

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

### 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

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