

Scientific Documentation

Tranexamic Acid, USP

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



Table of Contents

Product Specification
Certificate of Analysis
Safety Data Sheet (SDS)
Certification of Current Good Manufacturing Practices (cGMP)
Manufacturing Process Flowchart
Technical Statements
Elemental Impurities Statement
Residual Solvents Statement
General Label Information – Sample Label

Specification for Tranexamic Acid, USP (T4046)

Item Number	T4046
Item	Tranexamic Acid, USP
CAS Number	1197-18-8
Molecular Formula	C ₈ H ₁₅ NO ₂
Molecular Weight	157.21
MDL Number	
Synonyms	trans-4-(Aminomethyl)-cyclohexanecarboxylic Acid ; AMCA

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY (DRIED BASIS)	98.0	102.0 %
CHLORIDE		0.014 %
LOSS ON DRYING		0.5 %
RESIDUE ON IGNITION		0.1 %
ORGANIC IMPURITIES:		
TRANEXAMIC ACID RELATED COMPOUND C		0.1 %
AMINOMETHYL-BENZOIC ACID		0.1 %
cis-TRANEXAMIC ACID		0.2 %
DITRANEXAMIC ACID AMINE		0.1 %
ANY INDIVIDUAL, UNSPECIFIED IMPURITY		0.05 %
TOTAL IMPURITIES		0.2 %
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD	
EXPIRATION DATE		
DATE OF MANUFACTURE		
MONOGRAPH EDITION		
RESIDUAL SOLVENTS	AS REPORTED	

Spectrum Chemical Mfg Corp

<i>Corporate Headquarters:</i>	<i>West Coast Facility:</i>
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	T4046	Lot Number	1MH0263
Item	Tranexamic Acid, USP	Manufacturer Lot	X2307024M
CAS Number	1197-18-8	Manufacturer Code	5704
Molecular Formula	C ₈ H ₁₅ NO ₂	Molecular Weight	157.21

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			WHITE POWDER
ASSAY (DRIED BASIS)	98.0	102.0 %	100.0 %
CHLORIDE		0.014 %	<0.014 %
LOSS ON DRYING		0.5 %	0.1 %
RESIDUE ON IGNITION		0.1 %	0.0 %
ORGANIC IMPURITIES:			.
TRANEXAMIC ACID RELATED COMPOUND C		0.1 %	0.0 %
AMINOMETHYL-BENZOIC ACID		0.1 %	0.0 %
cis-TRANEXAMIC ACID		0.2 %	0.0 %
DITRANEXAMIC ACID AMINE		0.1 %	0.0 %
ANY INDIVIDUAL, UNSPECIFIED IMPURITY		0.05 %	0.00 %
TOTAL IMPURITIES		0.2 %	<0.2 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
IDENTIFICATION (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD
EXPIRATION DATE			15-JUL-2028
DATE OF MANUFACTURE			16-JUL-2023
MONOGRAPH EDITION			(USP-NF) 2023

TEST	SPECIFICATION		RESULT
	MIN	MAX	
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 2 (solvent) / CHLOROBENZENE			<360 ppm (M)
CLASS 2 (solvent) / XYLENE			<2170 ppm (M)
CLASS 3 (solvent) / ETHANOL			<5000 ppm (M)
NOTE: All results reported with (M) are from manufacturer certificate of analysis			.

Certificate of Analysis Results Entered By:

HBERMUDEZ
Hernan Bermudez
02-OCT-23 09:21:36

Certificate of Analysis Results Approved By:

SHANSEN
Selin Hansen
02-OCT-23 09:52:56

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



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.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Hunan Dongting Pharmaceutical Co., Ltd. at No. 16 Dongyan Road, Deshan, Changde City, Hunan 415001, China (CHN). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

SAFETY DATA SHEET

spectrum®



Revision date 05-June-2020

Revision Number 1

1. Identification

Product identifier

Product Name TRANEXAMIC ACID, USP

Other means of identification

Product Code(s) T4046

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Address

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

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Hazard statements

Appearance No information available **Physical state** No information available **Odor** No information available

Other information

No information available.

3. Composition/information on ingredients

Substance

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

Description of first aid measures

Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water.
Ingestion	Clean mouth with water and drink afterwards plenty of water.

Most important symptoms and effects, both acute and delayed

Symptoms	No information available.
----------	---------------------------

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.
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	Ensure adequate ventilation.
----------------------	------------------------------

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.
--------------------------------	--

Conditions for safe storage, including any incompatibilities

Storage Conditions	Keep container tightly closed in a dry and well-ventilated place.
---------------------------	---

8. Exposure controls/personal protection

Control parameters

Exposure Limits	This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
------------------------	---

Appropriate engineering controls

Engineering controls	Showers Eyewash stations Ventilation systems.
-----------------------------	---

Individual protection measures, such as personal protective equipment

Eye/face protection	No special protective equipment required.
Skin and body protection	No special protective equipment required.
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	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	No information available
Appearance	No information available
Color	No information available
Odor	No information available
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	no data available	None known
Melting point / freezing point	no data available	None known
Boiling point / boiling range	no data available	None known
Flash point	no data available	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known

Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	no data available	None known
Water solubility	No data available	None known
Solubility(ies)	no data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known
<u>Other information</u>		
Explosive properties	No information available	
Oxidizing properties	No information available	
Softening point	No information available	
Molecular weight	No information available	
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	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	No information available.
-----------------	---------------------------

Acute toxicity

Numerical measures of toxicity	No information available
---------------------------------------	--------------------------

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

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
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
------------	---------------

15. Regulatory information

International Inventories

TSCA	Not listed
-------------	------------

Note	*Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements
-------------	--

DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	This product complies with ENCS:
IECSC	This product complies with China:
KECL	Complies
PICCS	Complies
AICS	This product does not comply with 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 0

Flammability 0

Instability 0

Physical and chemical properties -

HMIS**Health hazards** 0**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) (AEL(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

05-June-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
T4046	Tranexamic Acid, USP

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,

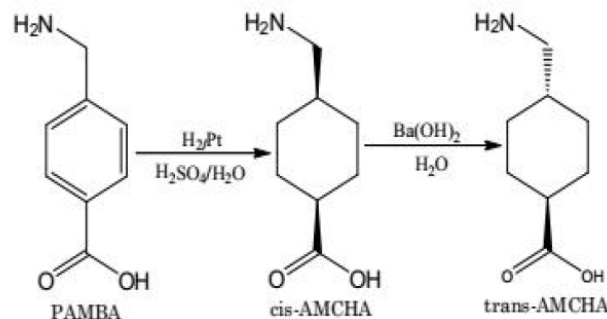
A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Tranexamic Acid, USP - T4046

Synthesis Route:



Brief description of the manufacturing process

The current manufacturing process of Tranexamic acid consists of three stages in sequence as follows:

- 1) Hydrogenation of 4-aminomethylbenzoic acid, which is composed of two steps: hydrogenation, and filtration.
- 2) Transformation from cis-Tranexamic acid to trans-Tranexamic acid, which is composed of five steps: cis-neutralization, trans-transformation, trans-neutralization, centrifugation, concentration and crystallization.
- 3) Purification of crude Tranexamic acid, which is composed of refining, filtration, crystallization, centrifugation, washing, and drying.

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

T4046, Tranexamic Acid, USP

Source Statement

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

BSE/TSE Statement

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

Allergen Statement

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

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

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

GMO Statement

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

Melamine Statement

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

Nitrosamine Statement

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

Animal Testing Statement

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

Organic Compliance Statement

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

Shelf Life Statement

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

Other Chemicals Statement

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

- | | |
|---------------------|-----------------|
| • Aflatoxins | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |

RE: Elemental Impurities- Tranexamic Acid, USP (Cat# T4046)

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. Per the current supply chain, the following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	<0.5 ppm
Lead	Pb	1	<0.5 ppm
Arsenic	As	1	<1.5 ppm
Mercury	Hg	1	<3.0 ppm
Cobalt	Co	2A	<5.0 ppm
Vanadium	V	2A	<10.0 ppm
Nickel	Ni	2A	<20.0 ppm
Platinum	Pt	2B	<10.0 ppm
Lithium	Li	3	<55.0 ppm
Antimony	Sb	3	<120 ppm
Barium	Ba	3	<140 ppm
Copper	Cu	3	<300 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. 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.

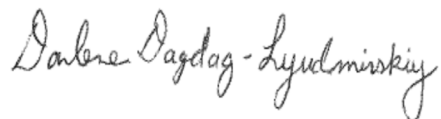
CORPORATE HEADQUARTERS

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

Sincerely,



Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfg. Corp.

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 - Tranexamic Acid, USP (Cat# T4046)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The Class 2 solvent, chlorobenzene, is present in the above mentioned material below the limit of 360 ppm. The Class 2 solvent, Xylene, is present in the above mentioned material below the limit of 2170 ppm. The Class 3 solvent, ethanol, is present in the above mentioned material below the limit of 5000 ppm. The other residual solvent, Ethyl propionate, is present in the above mentioned material below the limit of 5000 ppm.

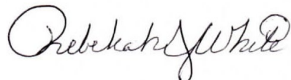
These limit complies with the requirements of the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline.

No Class 1 or other solvents are used or produced in the manufacture of this product.

1) Tranexamic Acid, USP – T4046

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,



Rebekah J. White
Technical Service Representative
Spectrum Chemical Mfg. Corp.

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

- Causes serious eye irritation • Causes skin irritation • May cause respiratory irritation.
- Wear protective gloves, eye protection, face protection • Avoid breathing dust • Use only outdoors or in a well-ventilated area • 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. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or physician if you feel unwell.

KEEP FROM CHILDREN

WARNING:
Cancer and Reproductive Harm-
www.P65Warnings.ca.gov



T4046 **SIZ SY**

Tranexamic Acid
[*trans*-4-(Aminomethyl)-
cyclohexanecarboxylic Acid]

USP
CAS 1197-18-8

CAUTION: For manufacturing, processing, repacking, or for prescription compounding. Rx only.
Read and understand the label and Safety Data Sheet (SDS) prior to use.

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

$C_8H_{15}NO_2$ F.W. 157.21

Manufacturer/Supplier Code ?
Manufacturer Lot Number ?

Assay (Dried Basis) 98.0-102.0%

MAXIMUM LIMITS

Chloride 0.014%
Loss on Drying 0.5%
Residue on Ignition 0.1%

Organic Impurities:

Tranexamic Acid Related Compound C	0.1%
Aminomethylbenzoic Acid	0.1%
<i>cis</i> -Tranexamic Acid	0.2%
Ditraxamic Acid Amine	0.1%
Any Individual Unspecified Impurity	0.05%
Total Impurities	0.2%
Elemental Impurities	As reported
Residual Solvents	To pass test

Repackaged by Spectrum as:

G 2/K5GHS-A ? Lot No. XQ####

Exp. Date: 00-00-0000



* 4 9 4 5 2 T 4 0 4 6 *

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