

Scientific Documentation

Tetracaine Hydrochloride, 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



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Specification for Tetracaine Hydrochloride, USP (TE128)

Item Number	TE128
Item	Tetracaine Hydrochloride, USP
CAS Number	136-47-0
Molecular Formula	$C_{15}H_{24}N_2O_2 \cdot HCl$
Molecular Weight	300.82
MDL Number	
Synonyms	2-Dimethylaminoethyl 4-butylaminobenzoate Hydrochloride

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS BASIS)	98.0	102.0 %
WATER DETERMINATION		2.0 %
RESIDUE ON IGNITION		0.1 %
ORGANIC IMPURITIES:		
AMINOBENZOIC ACID ^a		0.4 %
TETRACAINE HYDROCHLORIDE RELATED COMPOUND B		0.4 %
TETRACAINE HYDROCHLORIDE RELATED COMPOUND C		0.4 %
INDIVIDUAL UNSPECIFIED IMPURITY		0.4 %
TOTAL IMPURITIES		0.8 %
ELEMENTAL IMPURITIES		AS REPORTED
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	POSITIVE FOR CHLORIDE	
IDENTIFICATION (C)	RETENTION TIME CORRESPONDS TO STANDARD	
APPEARANCE		
EXPIRATION DATE		
DATE OF MANUFACTURE		

Test	Specification	
	Min	Max
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	TE128	Lot Number	4MK0056
Item	Tetracaine Hydrochloride, USP	Manufacturer Lot	TH0110623
CAS Number	136-47-0	Manufacturer Code	13524
Molecular Formula	C ₁₅ H ₂₄ N ₂ O ₂ •HCl	Molecular Weight	300.82

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (ANHYDROUS BASIS)	98.0	102.0 %	98.8 %
WATER DETERMINATION		2.0 %	0.02 %
RESIDUE ON IGNITION		0.1 %	0.03 %
ORGANIC IMPURITIES:			.
AMINO BENZOIC ACID ^a		0.4 %	<0.4 %
TETRACAINE HYDROCHLORIDE RELATED COMPOUND B		0.4 %	<0.4 %
TETRACAINE HYDROCHLORIDE RELATED COMPOUND C		0.4 %	<0.4 %
INDIVIDUAL UNSPECIFIED IMPURITY		0.4 %	<0.4 %
TOTAL IMPURITIES		0.8 %	<0.8 %
ELEMENTAL IMPURITIES		AS REPORTED	NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	POSITIVE FOR CHLORIDE		POSITIVE FOR CHLORIDE
IDENTIFICATION (C)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD
APPEARANCE			WHITE CRYSTALLINE POWDER
EXPIRATION DATE			01-MAY-2028
DATE OF MANUFACTURE			01-JUN-2023
RESIDUAL SOLVENTS		AS REPORTED	.

TEST	SPECIFICATION		RESULT
	MIN	MAX	
CLASS 2 (solvent) / HEXANE			<290 ppm
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm
CLASS 2 (solvent) / TOLUENE			<890 ppm
CLASS 3 (solvent) / ACETONE			<5000 ppm
MONOGRAPH EDITION			USP 2023

Certificate of Analysis Results Entered By:

GHERRERA
Genaro Herrera
23-FEB-24 06:42:24

Certificate of Analysis Results Approved By:

MCAMACHO
Matheu Camacho
23-FEB-24 06:45:02

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



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.

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 Venkata Narayana Active Ingredients Private Limited at No. 69, Chandrapadiya Village Vinjamur Mandal, SPSR Nellore, Andhra Pradesh 524228, India (IND). 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 11-November-2022

Revision Number 2

1. Identification

Product identifier

Product Name TETRACAINE HYDROCHLORIDE, USP

Other means of identification

Product Code(s) TE128

UN/ID no UN2811

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Address

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

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

Acute toxicity - Oral	Category 3
Serious eye damage/eye irritation	Category 2A
Skin sensitization	Category 1A

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

Toxic if swallowed
Causes serious eye irritation
May cause an allergic skin reaction



Appearance Crystalline powder

Physical state Solid

Odor No information available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
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
If skin irritation or rash occurs: Get medical advice/attention
Wash contaminated clothing before reuse
IF SWALLOWED: Immediately call a POISON CENTER or doctor
Rinse mouth

Precautionary Statements - Storage

Store locked up.

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%
Tetracaine Hydrochloride	136-47-0	100

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.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.
Skin contact	Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician.
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get medical attention.

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

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

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

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Store locked up.

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.

Skin and body protection Wear suitable protective 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 Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid
Appearance Crystalline powder
Color White
Odor No information available
Odor threshold No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	4.5-6.5 (1%)	None known
Melting point / freezing point	148 °C / 298.4 °F	None known
Boiling point / boiling range	no data available	None known
Flash point	>100 °C / °F	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive 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	Soluble in water	None known
Solubility(ies)	Soluble in Ethanol	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

Other information

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

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. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.
Skin contact	May cause sensitization by skin contact. Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components). May cause irritation. Prolonged contact may cause redness and irritation.
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Toxic if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	Itching. Rashes. Hives. May cause redness and tearing of the eyes.
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Acute toxicity

Numerical measures of toxicity	No information available
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Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	May cause skin irritation.
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.
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 microorganisms	Crustacea
Tetracaine Hydrochloride 136-47-0	-	-	-	1.49 mg/L EC50 Daphnia magna 48h

Persistence and degradability	No information available.
Bioaccumulation	Inherently biodegradable.

Other adverse effects	No information available.
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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

UN/ID no	UN2811
Proper Shipping Name:	Toxic solids, organic, n.o.s.
Hazard class	6.1
Packing group:	III
Special Provisions	IB8, IP3, T1, TP33
Marine Pollutant	Severe Marine Pollutant
Description:	UN2811, Toxic solids, organic, n.o.s., 6.1, III
Emergency Response Guide Number	154

TDG

UN-No:	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Hazard class	6.1
Packing Group:	III
Special Provisions	16
Description:	UN2811, Toxic solid, organic, n.o.s., 6.1, III

MEX

UN-No	UN2811
Proper Shipping Name	Toxic solid, organic, n.o.s.

Hazard class	6.1
Special Provisions	223, 274
Packing Group	III
Description	UN2811, Toxic solid, organic, n.o.s., 6.1, III

ICAO (air)

UN-No:	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Hazard class	6.1
Packing Group:	III
Special Provisions	A3, A5
Description:	UN2811, Toxic solid, organic, n.o.s., 6.1, III

IATA

UN number	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Transport hazard class(es)	6.1
Packing group	III
ERG Code	6L
Special Provisions	A3, A5
Description:	UN2811, Toxic solid, organic, n.o.s., 6.1, III

IMDG

UN number	UN2811
Proper shipping name	Toxic solid, organic, n.o.s.
Transport hazard class(es)	6.1
Packing group	III
EmS-No	F-A, S-A
Special Provisions	223, 274
Marine pollutant	NP1
Description	UN2811, Toxic solid, organic, n.o.s., 6.1, III

RID

UN number	UN2811
Proper Shipping Name:	TOXIC SOLID, ORGANIC, N.O.S.
Transport hazard class(es)	6.1
Packing group	III
Classification code	T2
Special Provisions	274, 614
Description:	UN2811, TOXIC SOLID, ORGANIC, N.O.S., 6.1, III
Labels	6.1

ADR

UN number	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Transport hazard class(es)	6.1
Packing group	III
Classification code	T2
Tunnel restriction code	(E)
Special Provisions	274, 614
Description:	UN2811, Toxic solid, organic, n.o.s., 6.1, III, (E)
Labels	6.1

ADN

UN/ID No	UN2811
Proper shipping name	Toxic solid, organic, n.o.s.
Transport hazard class(es)	6.1
Packing Group	III
Classification code	T2
Special Provisions	274, 614, 802
Description	UN2811, Toxic solid, organic, n.o.s., 6.1, III
Hazard label(s)	6.1
Limited quantity (LQ)	5 kg
Equipment Requirements	PP, EP

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 does not comply with china:

KECL Does not Comply

PICCS Does not Comply

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) (AELG(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

11-November-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
TE128	Tetracaine Hydrochloride, 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

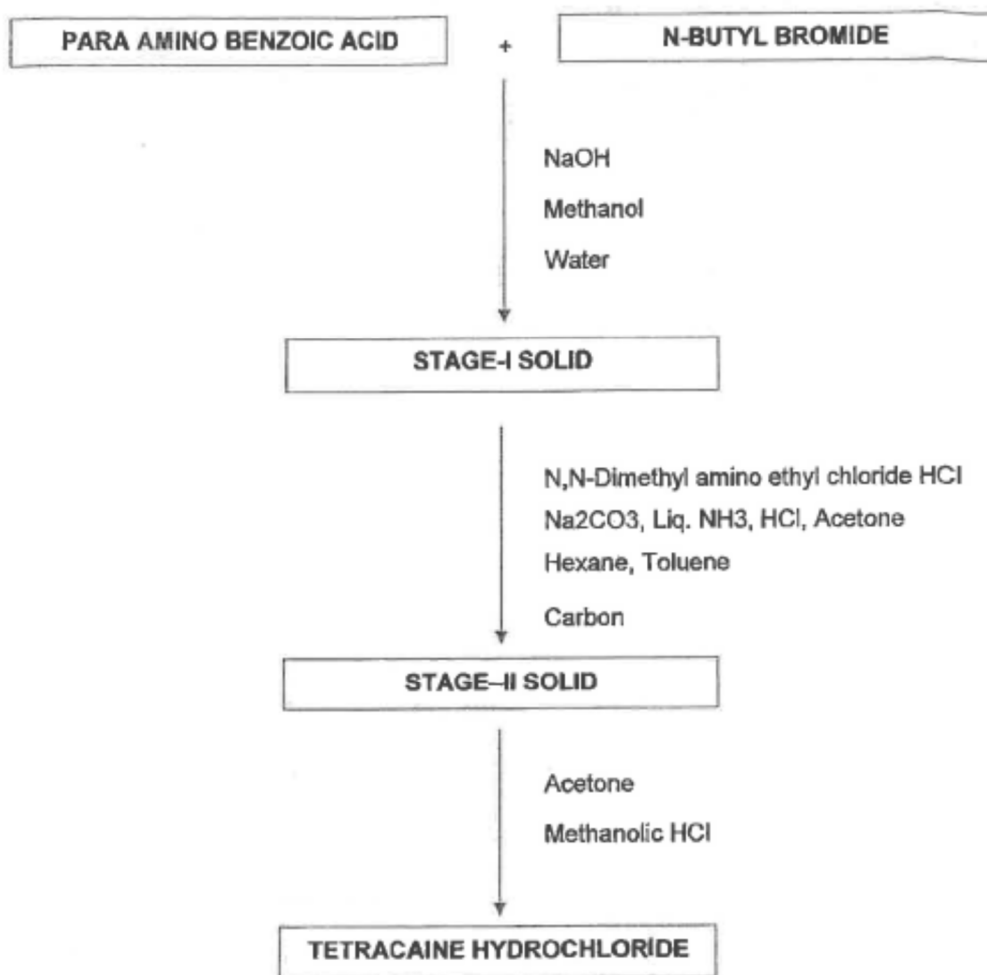
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

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 Tetracaine Hydrochloride, USP (Cat# TE128)



CORPORATE HEADQUARTERS

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WEST COAST FACILITY

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Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

TE128, Tetracaine Hydrochloride, 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 - Tetracaine Hydrochloride, USP (Cat# TE128)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

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PHONE 310.516.8000
FAX 310.516.9843



RE: Residual Solvents - Tetracaine Hydrochloride, USP (Cat# TE128)

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
Hexane	2	< 290 ppm
Methanol	2	< 3000 ppm
Toluene	2	< 890 ppm
Acetone	3	< 5000 ppm

* 1,4-Dioxane is present below the limit of 10 µg/g under the specification *Limit of Free Ethylene Oxide and Dioxane* as required by the NF monograph.

** Ethylene Glycol is present below the limit of 0.25% under the specification *Limit of Ethylene Glycol and Diethylene Glycol* as required by the NF monograph.

No Class 1 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
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CORPORATE HEADQUARTERS

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WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248


PHONE 310.516.8000

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Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.

Exp. Date: 00-00-0000



DANGER
 • Toxic if swallowed • Causes serious eye irritation • May cause an allergic skin reaction.
 • Do not eat, drink or smoke when using this product • Wear protective gloves, eye protection, face protection • Avoid breathing dust • Wash face, hands and any exposed skin thoroughly after handling • Contaminated work clothing must not be allowed out of the workplace.
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. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical attention. IF SWALLOWED: Immediately call a POISON CENTER or physician. Rinse mouth.

KEEP FROM CHILDREN



TE128

SIZ SY

Tetracaine Hydrochloride
 USP
 CAS 136-47-0

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

DOT: UN2811, Toxic solid, organic, n.o.s.
 (tetracaine hydrochloride), 6.1, PG III

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

$C_{15}H_{24}N_2O_2 \cdot HCl$ F.W. 300.82

Manufacturer/Supplier Code ?
 Manufacturer Lot Number ?

Assay (Anhydrous Basis) 98.0-102.0%
 MAXIMUM LIMITS

Water Determination 2.0%
 Residue on Ignition 0.1%

Organic Impurities:
 Aminobenzoic Acid 0.4%
 Tetracaine Hydrochloride Related Compound B 0.4%
 Tetracaine Hydrochloride Related Compound C 0.4%
 Individual Unspecified Impurity 0.4%
 Total Impurities 0.8%
 Elemental Impurities As reported
 Residual Solvents To pass test

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

Repackaged by Spectrum as:
 Lot No. XQ####

Spectrum Chemical Mfg Corp

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