# SAFETY DATA SHEET



#### 1. Identification

**Product identifier Tetracaine Hydrochloride** 

Other means of identification

Catalog number 1650006 136-47-0 **CAS** number

**Synonyms** Amethocaine hydrochloride

**Chemical name** Benzoic acid, 4-(butylamino)-, 2-(dimethylamino)ethyl ester, monohydrochloride

Specified quality tests and assay use only. Recommended use

Not for use as a drug. Not for administration to humans or animals. **Recommended restrictions** 

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name U. S. Pharmacopeia **Address** 12601 Twinbrook Parkway

> Rockville MD 20852-1790 **United States**

Telephone **RS Technical Services** 301-816-8129

Website www.usp.org E-mail RSTECH@usp.org

**Emergency phone number** CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

**Physical hazards** Not classified.

**Health hazards** Acute toxicity, oral Category 3

> Serious eye damage/eye irritation Category 2A Category 1 Sensitization, skin

Not classified. **Environmental hazards OSHA** defined hazards Not classified.

Label elements



Signal word Danger

Toxic if swallowed. May cause an allergic skin reaction. Causes serious eye irritation. **Hazard statement** 

**Precautionary statement** 

Avoid breathing dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Contaminated Prevention

work clothing must not be allowed out of the workplace. Wear eye protection/face protection.

Wear protective gloves.

If swallowed: Immediately call a poison center/doctor. Rinse mouth. If on skin: Wash with plenty of Response

water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. 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.

Store locked up. Storage

Dispose of contents/container in accordance with local/regional/national/international regulations. **Disposal** 

Material name: Tetracaine Hydrochloride USP SDS US Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information

Pharmacologically active material.

# 3. Composition/information on ingredients

#### **Substance**

Chemical name	Common name and synonyms	CAS number	%
Tetracaine Hydrochloride	Amethocaine hydrochloride	136-47-0	100

### 4. First-aid measures

Inhalation If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.

Call a physician if symptoms develop or persist.

Remove contaminated clothing immediately and wash skin with soap and water. In case of Skin contact

eczema or other skin disorders: Seek medical attention and take along these instructions. Get

medical attention if irritation develops and persists.

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Eye contact

Continue rinsing. Get medical attention if irritation develops and persists.

Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. Ingestion

Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Get medical attention if symptoms occur.

Pharmacologically active material. Occupational exposure may cause physiological effects.

Most important

symptoms/effects, acute and

delayed

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically.

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from General information

> an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must

receive immediate medical attention.

# 5. Fire-fighting measures

Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding Suitable extinguishing media

materials.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

Fire fighting

equipment/instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area.

Firefighters should use self-contained breathing equipment and protective clothing.

Use standard firefighting procedures and consider the hazards of other involved materials. Specific methods

General fire hazards No unusual fire or explosion hazards noted.

### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

**Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

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## 7. Handling and storage

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of Precautions for safe handling

dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage.

including any incompatibilities

Store in tight container as defined in the USP-NF. This material should be handled and stored per

label instructions to ensure product integrity.

# 8. Exposure controls/personal protection

#### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

#### **Exposure limit values**

**Industrial Use** 

Material	Туре	Value	
Tetracaine Hydrochloride (CAS 136-47-0)	TWA	10 micrograms/m3	

**Biological limit values** 

No biological exposure limits noted for the ingredient(s).

Appropriate engineering

controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

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

Eye/face protection Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary.

Base the choice of protection on the job activity and potential for contact with eyes or face. An

emergency eye wash station should be available.

Skin protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved **Hand protection** 

or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of

skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do

not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection Respirators are generally not required for laboratory operations. Use a tight-fitting full-face

respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task

and the level of existing engineering controls.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of reference standards.

Procedures for any other uses or quantities should be determined after an appropriate

assessment.

# 9. Physical and chemical properties

Appearance descriptions are general information and not specific to any USP lot. **Appearance** 

Solid. Physical state

Crystalline powder. **Form** 

White. Color Odorless. Odor **Odor threshold** Not available. Not available.

Melting point/freezing point 273.2 - 302 °F (134 - 150 °C)

Initial boiling point and boiling

range

Not available.

Not available. Flash point Not available. **Evaporation rate** Not available. Flammability (solid, gas)

Material name: Tetracaine Hydrochloride 1650006 Version #: 05 Revision date: 11-27-2019 Issue date: 10-13-2006 Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not available.

Flammability limit - upper

(%)

Not available.

Explosive limit - lower (%) Not available. Not available. Explosive limit - upper (%)

< 0.0000001 kPa at 25 °C Vapor pressure

Vapor density Not available. Not available. Relative density

Solubility(ies)

Solubility (water) Very soluble.

Solubility (other) Acetone: Practically insoluble.

> Ether: Insoluble. Benzene: Insoluble. Alcohol: Soluble.

**Auto-ignition temperature** Not available. Not available. **Decomposition temperature Viscosity** Not available.

Other information

**Chemical family** O-Acyl-ethanolamine derivative.

Molecular formula C15H24N2O2 . HCI

300.82 Molecular weight

pH in aqueous solution 4.5 - 6.5 Solution: 1%

10. Stability and reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport. Reactivity

Material is stable under normal conditions. **Chemical stability** 

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Iodine. Acids. Strong oxidizing agents. Reducing agents. Strong bases. Alkaline metals. Incompatible materials **Hazardous decomposition** 

products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. Cl-.

### 11. Toxicological information

Information on likely routes of exposure

Inhalation Knowledge about health hazard is incomplete.

Skin contact May cause an allergic skin reaction.

Causes serious eye irritation. Based on information from therapeutic use, this material may Eye contact

cause: Central nervous system effects.

Ingestion Toxic if swallowed.

Symptoms related to the physical, chemical, and

toxicological characteristics Local anesthetics: Headache. Numbness. Neck or back pain. Chest pain. Change in vision. Slurred speech. Dizziness. Drowsiness. Weakness. Feeling hot or cold. Ringing in ears. Anxiety. Nervousness. Excitement. Confusion. Difficulty in breathing. Gastrointestinal disturbances.

Information on toxicological effects

**Acute toxicity** Toxic if swallowed.

**Product Species Test Results** 

Tetracaine Hydrochloride (CAS 136-47-0)

Oral

LD50 Mouse 160 mg/kg

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Material name: Tetracaine Hydrochloride

Serious eye damage/eye

irritation

Causes serious eye irritation.

Local effects

2 % Eye irritation Result: Moderate. Species: Rabbit

Respiratory or skin sensitization

**Respiratory sensitization** Knowledge about health hazard is incomplete.

**Skin sensitization** May cause an allergic skin reaction.

Contact dermatitis has been reported in the literature.

**Germ cell mutagenicity** Knowledge about mutagenicity is incomplete.

Mutagenicity

Ames test Result: Negative.

Result Negative.

Chromosome aberration Result: Negative.

Micronucleus test Result: Negative.

**Carcinogenicity** Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

**Reproductive toxicity** Knowledge about health hazard is incomplete.

Reproductivity

Developmental

Result: NOAEL=10mg/kg

Species: Rabbit Developmental

Result: NOAEL=5mg/kg

Species: Rat Fertility

Result: NOAEL= 7.5mg/kg

Species: Rat

Specific target organ toxicity -

single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity -

repeated exposure

Knowledge about health hazard is incomplete.

Aspiration hazard Based on available data, the classification criteria are not met.

Further information Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

**Ecotoxicity** The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability No data is available on the degradability of this substance.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation

potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

**Disposal instructions** Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the

user of the product to determine, at the time of disposal, whether the product meets RCRA criteria

for hazardous waste.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

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Waste from residues / unused

products

Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

# 14. Transport information

DOT

**UN** number UN2811

Toxic, solid, organic, n.o.s. (Tetracaine hydrochloride) **UN proper shipping name** 

Transport hazard class(es)

Class 6.1 Subsidiary risk Ш Packing group

**IATA** 

UN2811 **UN** number

UN proper shipping name

Transport hazard class(es)

Class 6.1 Subsidiary risk Ш Packing group

Passenger and cargo

aircraft

Other information

Allowed with restrictions.

Cargo aircraft only

Transport in bulk according to

Annex II of MARPOL 73/78 and

the IBC Code

Allowed with restrictions.

Not applicable.

DOT; IATA



**General information** It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

Toxic, solid, organic, n.o.s. (Tetracaine hydrochloride)

## 15. Regulatory information

**US federal regulations** 

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)** 

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

chemical

Yes

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Classified hazard categories

Acute toxicity (any route of exposure) Serious eye damage or eye irritation Respiratory or skin sensitization

Material name: Tetracaine Hydrochloride

# SARA 313 (TRI reporting)

Not regulated.

#### Other federal regulations

### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

#### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

Not regulated.

Inventory name

(SDWA)

Australia

Taiwan

## **US state regulations**

#### **California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

Australian Inventory of Chemical Substances (AICS)

#### International Inventories

Country(s) or region

Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

<sup>\*</sup>A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

10-13-2006 Issue date 11-27-2019 **Revision date** 

Version # 05

United States & Puerto Rico

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Taiwan Chemical Substance Inventory (TCSI)

Toxic Substances Control Act (TSCA) Inventory

human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained

herein.

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On inventory (yes/no)\*

Yes

Yes

No