

SAFETY DATA SHEET

1. **Identification**

Product Identifier: Tetracaine Hydrochloride Injection, USP

Synonyms: Amethocaine Hydrochloride

National Drug Code (NDC): 17478-045-32

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. **Hazard(s) Identification**

Physical Hazards: Not classifiable.

Health Hazards: Not classifiable.

Symbol(s): None.

Signal Word: None.

Hazard Statement(s): None.

Precautionary Statement(s): None.

Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. **Composition/Information on Ingredients**

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Tetracaine Hydrochloride	136-47-0	Amethocaine Hydrochloride	$C_{15}H_{24}N_2O_2 \cdot HCl$	300.82	1%

*The formula also contains Sodium Chloride, 7.5 mg; Sodium Hydroxide and/or Hydrochloric Acid may be added to adjust pH (3.2 – 6.0) and Water for Injection.

4. First Aid Measures

Ingestion:	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
Eye Contact:	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Skin Contact:	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	Inadvertent contact with this product may cause irritation, followed by numbness. Ingestion may cause numbness of the tongue and anesthetic effects on the stomach. In clinical use, this product produces numbness when injected. In normal clinical use, adverse effects may include fever, headaches, agitation, tingling of extremities, general hypotension, bradycardia, dizziness, nausea, vomiting, anemia, back pain, post-operative pain and fetal distress. Systemic absorption can produce central nervous system (CNS) stimulation and/or CNS depression. CNS depression may progress to coma and cardio-respiratory arrest. Signs of cardiovascular toxicity may include changes in cardiac conduction, excitability, refractoriness, contractility, and peripheral vascular resistance. Toxic blood levels may cause atrioventricular block, ventricular arrhythmias, cardiac arrest, and sometimes death. In addition, decreased cardiac output and arterial blood pressure may occur. Allergic-type reactions are rare but may

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occur due to sensitivity to the local anesthetic. These reactions are characterized by signs such as urticaria, pruritus, erythema, angioneurotic edema (including laryngeal, edema), tachycardia, sneezing nausea, vomiting, dizziness, syncope, excessive sweating, elevated temperature, and possibly, anaphylactic-like symptoms (including severe hypotension). Cross sensitivity with other ester-type local anesthetics may occur.

Medical Conditions Aggravated by Exposure:

Pre-existing hypersensitivity to Tetracaine or other local anesthetics. Pre-existing nervous system or cardiovascular ailments. Pre-existing ailments in the following organs: central nervous system, eyes, respiratory system, cardiovascular system and possibly skin.

Notes to Physician:

Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media:

Use water, carbon dioxide, dry chemical or foam as necessary.

Unsuitable Extinguishing Media:

Not determined.

Specific Hazards Arising from the Chemical:

Flammability:

Not anticipated from this aqueous product.

Hazardous Combustion Products:

Not determined.

Other Specific Hazards:

Not determined.

Special Protective Equipment/Precautions for Firefighters:

Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions:

Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment:

For personal protection see section 8.

Methods for Cleaning Up:

Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water.

Environmental Precautions:

No data available.

Reference to Other Sections:

Refer to Sections 8, 12 and 13 for further information.

7. **Handling and Storage**

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Specific End Use: Pharmaceuticals.

8. **Exposure Controls/Personal Protection**

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Tetracaine Hydrochloride	Not established.

Engineering Controls: Engineering controls are normally not needed during the normal use of this product.

Respiratory Protection: Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Eyes Protection: Not required for the normal use of this product. Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Not required for the normal use of this product. Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize

direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection: Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color:	Clear, colorless liquid.
Odor:	Odorless.
Odor Threshold:	No data available.
pH:	3.2 – 6.0.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	No data available.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	No data available.
Incompatible Materials:	Strong oxidizer, acids.
Hazardous Decomposition Products:	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (CO _x), nitrogen oxides (NO _x), and hydrogen chloride.
Hazardous Polymerization:	Not anticipated to occur with this product.

11. **Toxicological Information**

Information on the Likely Routes of Exposure:

Inhalation: May cause irritation to the respiratory system.

Ingestion: No data available.

Skin Contact: No data available.

Eye Contact: May cause eye irritation.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics:

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure:

No data available.

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Tetracaine Hydrochloride	Mouse	Oral	LD ₅₀	160 mg/kg
Tetracaine Hydrochloride	Rat	Intravenous	LD ₅₀	4.5 mg/kg
Tetracaine Hydrochloride	Mouse	Intravenous	LD ₅₀	6.4 mg/kg
Tetracaine Hydrochloride	Rabbit	Intravenous	LD ₅₀	2.2 mg/kg
Tetracaine Hydrochloride	Guinea Pig	Intravenous	LD ₅₀	4 mg/kg
Tetracaine Hydrochloride	Rat	Intraperitoneal	LD ₅₀	23.5 mg/kg
Tetracaine Hydrochloride	Mouse	Intraperitoneal	LD ₅₀	23 mg/kg
Tetracaine Hydrochloride	Rabbit	Intratracheal	LD ₅₀	4.4 mg/kg

Acute Toxicity – Dermal:

No data available.

Acute Toxicity – Inhalation:

No data available.

Corrosivity:

No data available.

Dermal Irritation:

None anticipated from normal handling of this product. Inadvertent contact with this product may be irritating to broken skin and mucous membranes, and may produce numbness. During topical use, mild erythema at the site of application is frequently seen with slight edema or pruritus occurring less commonly.

Eye Irritation:

None anticipated from normal handling of this product. During clinical use, a stinging sensation may occur when Tetracaine Hydrochloride is used in the eye. Inadvertent contact of this product with eyes may produce irritation, numbness, and blurred vision.

Derma or Respiratory Sensitization:

None anticipated from normal handling of this product. Inadvertent contact of this product with the respiratory system may produce irritation and numbness. Rarely, allergic-type reactions have been reported during the clinical use of Tetracaine Hydrochloride.

Toxicokinetics/Metabolism:

No data available.

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Target Organ Effects:	Based on clinical use, possible target organs include the nerves, central nervous system, respiratory system, eyes, cardiovascular system and possibly the skin.
Reproductive Effects:	Long-term reproduction studies in animals with Tetracaine Hydrochloride have not been conducted.
Carcinogenicity:	Long-term studies in animals to evaluate the carcinogenic potential of Tetracaine Hydrochloride have not been conducted.
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.
Mutagenicity:	Tetracaine hydrochloride was inconclusive in an Ames test for mutagenicity.
Aspiration Hazard:	None anticipated from normal handling of this product.

12. Ecological Information

Ecotoxicity

Aquatic:	No data available.
Terrestrial:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

15. **Regulatory Information**

US Federal Regulations:

Toxic Substance Control Act (TSCA): Not listed.

CERCLA Hazardous Substance and Reportable Quantity: Not listed.

SARA 313: Not listed.
SARA 302: Not listed.

State Regulations

California Proposition 65: Not listed.

16. **Other Information**

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