



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Prilocaine</b>
<b>Other means of identification</b>	
<b>Catalog number</b>	1560990
<b>CAS number</b>	721-50-6
<b>Synonyms</b>	O-propionotoluidide, 2-(propylamino)-
<b>Chemical name</b>	Propanamide, N-(2-methylphenyl)-2-(propylamino)-
<b>Recommended use</b>	For analytical laboratory use only.
<b>Recommended restrictions</b>	Not for use as a drug. Not for administration to humans or animals.

### Manufacturer/Importer/Supplier/Distributor information

#### Manufacturer

<b>Company name</b>	U. S. Pharmacopeia
<b>Address</b>	12601 Twinbrook Parkway Rockville MD 20852-1790 United States
<b>Telephone</b>	Technical Services 301-816-8129
<b>Website</b>	www.usp.org
<b>E-mail</b>	RSTECH@usp.org
<b>Emergency phone number</b>	CHEMTREC within US & 1-800-424-9300 Canada CHEMTREC outside US & +1 703-527-3887 Canada

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Acute toxicity, oral Category 4 Serious eye damage/eye irritation Category 2A
<b>Environmental hazards</b>	Not classified.
<b>OSHA defined hazards</b>	Not classified.

#### Label elements



<b>Signal word</b>	Warning
<b>Hazard statement</b>	Harmful if swallowed. Causes serious eye irritation.
<b>Precautionary statement</b>	
<b>Prevention</b>	Wash thoroughly after handling. Wear eye protection/face protection.
<b>Response</b>	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. 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.
<b>Storage</b>	Not available.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	Pharmacologically active material.

### 3. Composition/information on ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Prilocaine	O-propionotoluidide, 2-(propylamino)-	721-50-6	100

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

### 4. First-aid measures

<b>Inhalation</b>	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.
<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not induce vomiting without advice from poison control center.
<b>Most important symptoms/effects, acute and delayed</b>	Central nervous system effects. Methemoglobinemia. Pharmacologically active material. Occupational exposure may cause physiological effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically.
<b>General information</b>	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from 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

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No unusual fire or explosion hazards noted.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire fighting equipment/instructions</b>	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.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	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.
<b>Methods and materials for containment and cleaning up</b>	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.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

### 7. Handling and storage

<b>Precautions for safe handling</b>	As a general rule, when handling USP materials, avoid all contact and inhalation of 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.
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**Conditions for safe storage, including any incompatibilities**

Store in tight container. 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	Type	Value
Prilocaine (CAS 721-50-6)	STEL	5 mg/m3
	TWA	1 mg/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

##### Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved 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 USP materials.

## 9. Physical and chemical properties

### Appearance

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

#### Physical state

Solid.

#### Form

Powder.

#### Color

White. Off-white.

### Odor

Odorless.

### Odor threshold

Not available.

### pH

Not available.

### Melting point/freezing point

96.8 - 102.2 °F (36 - 39 °C)

### Initial boiling point and boiling range

318.2 - 323.6 °F (159 - 162 °C) at 1 mm Hg

### Flash point

Not available.

### Evaporation rate

Not available.

### Flammability (solid, gas)

Not available.

### Upper/lower flammability or explosive limits

#### Flammability limit - lower (%)

Not available.

#### Flammability limit - upper (%)

Not available.

#### Explosive limit - lower (%)

Not available.

#### Explosive limit - upper (%)

Not available.

<b>Vapor pressure</b>	0.000003 kPa (77 °F (25 °C))
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Slightly soluble.
<b>Solubility (other)</b>	Acetone: Very soluble. Ethanol: Very soluble.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Amino amide.
<b>Molecular formula</b>	C13H20N2O
<b>Molecular weight</b>	220.31

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	None known.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Knowledge about health hazard is incomplete.
<b>Skin contact</b>	Based on information from therapeutic use, this material may cause: Central nervous system effects. Cardiovascular effects.
<b>Eye contact</b>	Causes serious eye irritation.
<b>Ingestion</b>	Harmful if swallowed.

<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	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.
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### Information on toxicological effects

<b>Acute toxicity</b>	Harmful if swallowed.
<b>Skin corrosion/irritation</b>	Knowledge about health hazard is incomplete.
<b>Serious eye damage/eye irritation</b>	Causes serious eye irritation.
<b>Respiratory or skin sensitization</b>	
<b>Respiratory sensitization</b>	Knowledge about health hazard is incomplete.
<b>Skin sensitization</b>	Knowledge about health hazard is incomplete.
<b>Germ cell mutagenicity</b>	Knowledge about mutagenicity is incomplete.

#### Mutagenicity

In vitro chromosome aberration assay in human lymphocytes  
Result: Negative.  
In vivo mouse micronucleus assay  
Result: Negative.  
Salmonella reverse mutation Ames assay  
Result: Negative.

<b>Carcinogenicity</b>	Knowledge about carcinogenicity is incomplete.
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#### IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

## OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

## US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

**Reproductive toxicity** Based on available data, the classification criteria are not met.

### Reproductivity

300 mg/kg Reproductivity test, administered intramuscularly.

Result: No evidence of impaired fertility or harm to the fetus.

Species: Rat

40 mg/kg Reproductivity and development study,

administered subcutaneously.

Result: No teratogenicity, embryotoxicity, or fetotoxicity observed.

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

Product		Species	Test Results
Prilocaine (CAS 721-50-6)			
Aquatic			
Acute			
Algae	EC50	Algae	154 mg/l, 72 hours
Fish	LC50	Fish	188 mg/l, 96 hours

**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.

**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

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

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

## 15. Regulatory information

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

### Toxic Substances Control Act (TSCA)

#### 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 1910.1001-1053)

Not listed.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### SARA 302 Extremely hazardous substance

Not listed.

#### SARA 311/312 Hazardous chemical

Yes

**Classified hazard categories** Acute toxicity (any route of exposure)  
Serious eye damage or eye irritation

#### 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 (SDWA)

Not regulated.

### US state regulations

#### California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (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](http://www.P65Warnings.ca.gov).

### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
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)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*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

**Issue date** 10-29-2009

Material name: Prilocaine

1560990 Version #: 04 Revision date: 02-07-2022 Issue date: 10-29-2009

USP SDS US

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**Revision date**

02-07-2022

**Version #**

04

**Disclaimer**

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