



# SWATI SPENTOSE PVT. LTD. UNIT-I

Manufacturing Site Address: A-1/2102 & 2103, Phase-III, G.I.D.C, Vapi-396 195, Gujarat. India

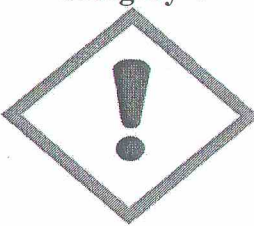
## Safety Data Sheet

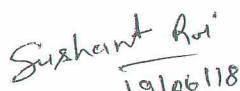
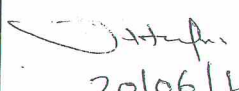
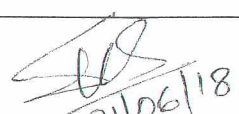
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Product Name: Prilocaine Hydrochloride	Page No.: 1 of 11

### 1.0 Product and company Identification:

GHS Product Identifier	Prilocaine hydrochloride
Other means of Identification	Procainamide, N-(2-methylphenyl)-2-(propyl amino)-monohydrochloride
Recommended use of the chemical and restrictions on use.	Local Anesthetic
Chemical Name:	Prilocaine hydrochloride
Chemical Formula:	C <sub>13</sub> H <sub>20</sub> N <sub>2</sub> O · HCl
RTECS:	UG5775000
EC-No.	217-244-0
Catalog Codes:	SLP1336
CAS#:	1786-81-8
TSCA: TSCA 8(b) inventory:	TSCA 8(b) inventory: Prilocaine HCl
Synonym:	Propitocaine hydrochloride
Supplier Details (Including name, address, phone number etc.)	Swati Spentose Pvt. Ltd. A-1/2102 & 2103, Phase-III, G.I.D.C, Vapi-396195. Gujarat, India.
Emergency Phone Number:	0260-2433133

### 2.0 Hazards Identification:

Hazards effects	<b>Prilocaine Hydrochloride</b>
	<b>HAZARDOUS IDENTIFICATION</b> <b>Acute Toxicity (Poison): Oral, Dermal, Inhalation</b>  <b>Category-4</b>   Acute toxicity: Harmful if swallowed. Skin irritation/corrosion: Causes skin irritation. Eye damage/irritation: Causes serious eye irritation.

Activity	Prepared By	Checked By	Approved By
Sign & Date	 19/06/18	 20/06/18	 21/06/18
Name & Designation	Mr. Sushant Rai Officer - EHS	Mr. Jitendra Varma Project & MNT - Head	Mr. S. K. Srivastava Corporate Head - QA & QC

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GHS label elements, including precautionary statements.

Classification of the substance or mixture GHS  
Classification in accordance with 29 CFR 1910 (OSHA HCS)

Label elements:

Labeling according to Regulation (EC) No. 1272/2008 The substance is classified and labeled according to the CLP regulation.

Hazard pictograms GHS07

Signal word Warning

Hazard statement(s)

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statement(s)

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 If on skin Wash with soap and water.

P305+P351+P338 IF IN EYES Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.


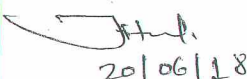
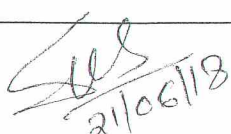
P362 Take off contaminated clothing and wash before reuse.

### 3.0 Composition/Information On Ingredients:

Component	CAS. No.	Weight
Prilocaine hydrochloride	1786-81-8	100%

### 4.0 First-aid-measures :

Description of necessary measures, subdivided according to the different routes of exposure, i.e., inhalation, skin	Eye Contact: Check for and remove any contact lenses. Flush with copious amounts of water for at least 15 minutes. Do not use an eye ointment as a first aid measure. Seek
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and eye contact and ingestion.	<p>medical attention.</p> <p><b>Skin Contact:</b> Remove contaminated clothing and shoes. Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. <b>Serious Skin Contact:</b> Not available. <b>Inhalation:</b> If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention. <b>Serious Inhalation:</b> Not available. <b>Ingestion:</b> Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband. <b>Serious Ingestion:</b> Not available.</p>
Indication of immediate medical attention and special treatment needed, if necessary	<p><b>Eye Contact:</b> Check for and remove any contact lenses. Flush with copious amounts of water for at least 15 minutes. Do not use an eye ointment as a first aid measure. Seek medical attention.</p> <p><b>Skin Contact:</b> Remove contaminated clothing and shoes. Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. <b>Serious Skin Contact:</b> Not available. <b>Inhalation:</b> If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention. <b>Serious Inhalation:</b> Not available. <b>Ingestion:</b> Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a</p>

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collar, tie, belt or waistband.

### 5.0 Fire Fighting Measures :

Suitable and unsuitable extinguishing media.

**Flammability of the Product:** May be combustible at high temperature.

**Auto-Ignition Temperature:** Not available.

**Flash Points:** Not available.

**Flammable Limits:** Not available.

**Products of Combustion:** Carbon oxides, Nitrogen oxides (NOx), Hydrogen chloride gas

**Fire Hazards in Presence of Various Substances:** Not available.

**Explosion Hazards in Presence of Various Substances:**

Risks of explosion of the product in presence of mechanical impact: Not available. Risks of explosion of the product in presence of static discharge: Not available.

**Fire Fighting Media and Instructions:**

SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

**Special Remarks on Fire Hazards:** Not available.

**Special Remarks on Explosion Hazards:** Not available.

Special Protective Equipment and precautions for fire-fights

**Personal Protection:**

Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

**Personal Protection in Case of a Large Spill:**

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Specific hazardous arising from the chemical

Not available

### 6.0 Accidental Release Measures:

Personal Precautions, Protective Equipment and emergency procedures.

**Personal Protection:** Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or

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equivalent. A respirator is not required for routine conditions of use of this product. Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place.

### Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist before handling this product.

### Methods and material for containment for and cleaning up.

**Small Spill:** Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

**Large Spill:** Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow evacuating through the sanitary system.

## 7.0 Handling and Storage :

### Precautions for safe handling.

#### Precautions:

Wear personal protective equipment. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation. Do not ingest.

### Conditions for safe storage, including any incompatibilities

**Storage:** Store in cool, well ventilated area. Keep container tightly closed. Avoid contact with water or humidity.

## 8.0 Exposure Controls/Personal Protection:

### Control limit

**Exposure Limits:** Not available.

### Appropriate engineering controls.

#### Engineering Controls:

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

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### Individual Protection measures, Such as personal protective equipment

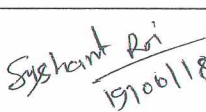
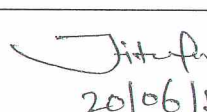
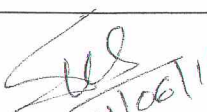
**Personal Protection:** Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. A respirator is not required for routine conditions of use of this product. Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).Gloves.

### Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist before handling this product.

## 9.0 Physical and Chemical Properties:

Appearance (Physical state, color, etc.)	Solid (crystalline powder)
Odor	Odorless
Color	White or almost white
Molecular Weight	256.77 g/mol
Odor Threshold	Not available
pH (1% soln./water)	Not applicable
Melting point/Freezing point	330.8 - 336.2 °F (166 - 169 °C)
Initial boiling point and boiling range	Not available
Flash Point	Not available
Evaporation Rate	Not available
Flammability (Solid, Gas)	Not available
Upper/Lower Flammability or Explosive Limits	Not available
Vapor Pressure	< 0.0000001 kPa at 25 °C
Vapor Density	Not available
Relative Density	Not available
Other Solubility	Freely soluble in ethanol; practically insoluble in diethyl ether; slightly soluble in chloroform; very slightly soluble in acetone.
Partition Coefficient	Not available
Auto-ignition Temperature	Not available

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Decomposition Temperature	Not available
Solubility in water	Freely soluble.

### 10.0 Stability and Reactivity Data:

Chemical Stability	Stable under recommended storage conditions.
Possibility of Hazardous reactions.	No dangerous reaction known under conditions of normal use.
Condition to avoid	Heat. Avoid dust formation. Incompatible materials.
Incompatible materials	Strong reducing agents
Special Remarks on Reactivity	Not available.
Hazards decomposition product	Carbon oxides, Nitrogen oxides (NOx), Hydrogen chloride gas

### 11.0 Toxicological Information:

Delayed and immediate effects and also chloric effects from shorts and long term exposure	<p><b>Chronic Effects on Humans:</b></p> <p><b>MUTAGENIC EFFECTS:</b> In vitro chromosome aberration assay in human lymphocytes Result: Negative. In vivo mouse micronucleus assay Result: Negative. Salmonella reverse mutation Ames assay Result: Negative.</p> <p><b>TERATOGENIC EFFECTS:</b> Not available.</p> <p><b>Other Toxic Effects on Humans:</b></p> <p>Hazardous in case of ingestion. Slightly hazardous in case of skin contact (irritant), of inhalation.</p> <p><b>Special Remarks on Toxicity to Animals:</b> Not available.</p> <p><b>Special Remarks on Chronic Effects on Humans:</b> May cause adverse reproductive effects and birth defects based on animal data.</p> <p><b>Special Remarks on other Toxic Effects on Humans:</b></p> <p>Acute Potential Health Effects: Skin: May cause skin irritation and numbness Eyes: May cause eye irritation and numbness</p> <p>Ingestion: Harmful if swallowed. May cause irritation and numbness of the gastrointestinal tract with nausea, vomiting, or abdominal discomfort. May cause blurred vision. May affect behavior (hallucinations, euphoria, convulsions, spasticity, drowsiness, somnolence, excitement, nervousness, dizziness, tremors, unconsciousness), cardiovascular system (low blood pressure, possible cardiac arrest)), respiration,</p>
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	and metabolism Inhalation: May cause respiratory tract irritation and numbness
Acute toxicity	LD50 Intraperitoneal - Rat - 148 mg/kg(Prilocaine hydrochloride) LD50 Intraperitoneal - Mouse - 30 mg/kg(Prilocaine hydrochloride) LD50 Intravenous - Mouse - 55 mg/kg(Prilocaine hydrochloride) LD50 Subcutaneous - Mouse - 632 mg/kg(Prilocaine hydrochloride)
Other Toxic Effects on Humans	Hazardous in case of ingestion. Slightly hazardous in case of skin contact (irritant), of inhalation
Special Remarks on Toxicity to Animals	Not available.
Special Remarks on Chronic Effects on Humans	Not available.
Special Remarks on other Toxic Effects on Humans:	<b>Acute Potential Health Effects:</b> Skin: May cause skin irritation and numbness Eyes: May cause eye irritation and numbness. Ingestion: Harmful if swallowed. May cause irritation and numbness of the gastrointestinal tract with nausea, vomiting, or abdominal discomfort. May cause blurred vision. May affect behavior (hallucinations, euphoria, convulsions, spasticity, drowsiness, somnolence, excitement, nervousness, dizziness, tremors, unconsciousness) , cardiovascular system (low blood pressure, possible cardiac arrest)), respiration, and metabolism Inhalation: May cause respiratory tract irritation and numbness
Toxicity to Animals	LC50/inhalation/rat: Not available. LD50/oral/mouse: Not available. LC50/inhalation/mouse: Not available. LD50/oral/rat: Not available. LC50information: Not available. LD50/dermal/rat: Not available.
Routes of Entry	Dermal contact. Eye contact. Inhalation. Ingestion.
<b>12.0 Ecological information:</b>	
Eco toxicity (aquatic and terrestrial, where available).	Eco toxicity: Not available.

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Persistence and degradability	<p><b>Products of Biodegradation:</b> Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.</p> <p><b>Toxicity of the Products of Biodegradation:</b> The products of degradation are more toxic.</p>
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### 13.0 Disposal Consideration:

Description of waste residues and information on their safe handling and methods of disposal, including any contaminated packing.	This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). 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. Dispose in accordance with all applicable regulations.
Waste Disposal:	Waste must be disposed of in accordance with federal, state and local environmental control regulations. Empty containers should be taken for local recycling, recovery or waste disposal.

### 14.0 Transport Information:

UN Number	Not applicable
UN Proper Shipping Name	Not regulated as dangerous goods.
DOT Classification	Not regulated as dangerous goods.
Identification	Not applicable
Transport regulation/UN Classification	Not applicable
Transport Hazard Class (es).	Not applicable
IATA/ICAO(air)	Not regulated as dangerous goods.
ADR/RID(road/Railway)	Not applicable
IMDG (sea)	Not regulated as dangerous goods.

### 15.0 Other Regulatory Information:

Safety, Health and environment for the products in question	US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. One or more components are not listed on TSCA.
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### R and S Phrases:

#### Risk phrases:

R22 - Harmful if swallowed.

R36/38 - Irritating to eyes and skin.

#### Safety phrases:

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S37 - Wear suitable gloves.

S46 - If swallowed, seek medical advice immediately and show this container or label.

European Regulatory Information: 1272/2008

### H and P Phrases:

#### Hazard Statements:

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H412 Harmful to aquatic life with long lasting effects.

#### Precautionary Statements:

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 If on skin Wash with soap and water.

P305+P351+P338 IF IN EYES Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.

P362 Take off contaminated clothing and wash before reuse.

#### HMIS (U.S.A.):

Health Hazard: 3

Fire Hazard: 1

Personal Protection: E

National Fire Protection Association (U. S.A.): Health: 2

Flammability: 1

Reactivity: 0

#### Protective Equipment:

Gloves. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Splash goggles

#### Other Regulations:

OSHA: Hazardous by definition of Hazard Communication

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	Standard (29 CFR 1910.1200). EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances. <b>Other Classifications:</b> WHMIS (Canada): CLASS D-2B: Material causing other toxic effects (TOXIC).
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### 16.0 Other Information:

References and Other information including information on preparation and revision of SDS	This data is furnished gratuitously independent of any sales of the product and only for your investigation and independent verification. While the information is believed to be correct, <b>Swati Spentose Private Limited</b> shall in no event be any responsible for any damage whatever, directly or indirectly resulting in the use of or reliance upon data contained herein. No warranty, either expressed or implied, or merchantability, of fitness, or of any nature with respect to the product, or to the data is made herein. You are urged to obtain data sheet for all <b>Swati Spentose Private limited</b> product you buy, process, use or distribute, and encouraged to advise anyone working with or exposed such products of the information contained herein.
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### Abbreviation:

CAS	Chemical Abstract Service Number
RTECS	Registry of Toxic Effects of Chemical Substances
DOT	Department of Transportation
UN	United Nations
LD	Lethal dose
IATA	International Air Transport Association

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