

# Scientific Documentation

## Prilocaine Hydrochloride, USP

Not appropriate for regulatory submission.

Please visit [www.spectrumchemical.com](http://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 Prilocaine Hydrochloride, USP (PR102)

Item Number	PR102
Item	Prilocaine Hydrochloride, USP
CAS Number	1786-81-8
Molecular Formula	C <sub>13</sub> H <sub>20</sub> N <sub>2</sub> O•HCl
Molecular Weight	256.77
MDL Number	
Synonyms	Propitocaine Hydrochloride

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0%	102.0 %
LOSS ON DRYING		0.3 %
RESIDUE ON IGNITION		0.1 %
ELEMENTAL IMPURITIES	AS REPORTED	
ORGANIC IMPURITIES:		
RELATED COMPOUND A		0.01 %
INDIVIDUAL UNSPECIFIED IMPURITY		0.10 %
TOTAL IMPURITIES		0.2 %
IDENTIFICATION A ( FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	POSITIVE FOR CHLORIDE	
IDENTIFICATION (C)	RETENTION TIME MATCHES STANDARD	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	AS REPORTED	

*Spectrum Chemical Mfg Corp*

**Corporate Headquarters:** 769 Jersey Ave.  
**West Coast Facility:** 14422 S. San Pedro St.

***Spectrum Chemical Mfg Corp***

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***Corporate Headquarters:***    ***West Coast Facility:***

New Brunswick, NJ 08901    Gardena, CA 90248

732.214.1300

310.516.8000

## Certificate Of Analysis

Item Number	PR102	Lot Number	2MA0288
Item	Prilocaine Hydrochloride, USP	Manufacturer Lot	109980
CAS Number	1786-81-8	Manufacturer Code	15012
Molecular Formula	C <sub>13</sub> H <sub>20</sub> N <sub>2</sub> O•HCl	Molecular Weight	256.77

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	98.0%	102.0 %	100.8 %
LOSS ON DRYING		0.3 %	0.0 %
RESIDUE ON IGNITION		0.1 %	0.1 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
ORGANIC IMPURITIES:			.
RELATED COMPOUND A		0.01 %	0.00 %
INDIVIDUAL UNSPECIFIED IMPURITY		0.10 %	0.00 %
TOTAL IMPURITIES		0.2 %	0.0 %
IDENTIFICATION A ( FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	POSITIVE FOR CHLORIDE		POSITIVE FOR CHLORIDE
IDENTIFICATION (C)	RETENTION TIME MATCHES STANDARD		RETENTION TIME MATCHES STANDARD
EXPIRATION DATE			30-SEP-2024
DATE OF MANUFACTURE			01-SEP-2021
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 2 (solvent) / HEXANE			<290 ppm
CLASS 3 (solvent) / ACETONE			<5000 ppm
CLASS 2 (solvent) / TOLUENE			<890 ppm

Certificate of Analysis Results Entered By:

SVANGOOR  
Swetha Vangoor  
15-FEB-23 14:52:19

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS  
Allison Williams  
15-FEB-23 14:52:29

**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, repackaging 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 Nortec Quimica SA at Rua Dezessete, 200 Distrito Industrial de Duque de Caxias, Duque de Caxias, Rio de Janeiro 25250612, Brazil (BRA). 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

Preparation Date: 9/18/2017

Revision date 1/29/2019

Revision Number: G2

### 1. IDENTIFICATION

#### Product identifier

**Product code:** PR102  
**Product Name:** PRILOCAINE HYDROCHLORIDE, USP

#### Other means of identification

**Synonyms:** o-Propionotoluidide, 2-(propylamino)-, monohydrochloride  
 Propanamide, N-(2-methylphenyl)-2-(propylamino)-, monohydrochloride  
 Propitocaine hydrochloride  
 alpha-Propylamine-2-methyl-propionanilide hydrochloride  
 2-(Propylamino)-o-propionotoluidide hydrochloride

**CAS #:** 1786-81-8  
**RTECS #** UG5775000  
**CI#:** Not available

#### Recommended use of the chemical and restrictions on use

**Recommended use:** Topical anesthetic. Local anesthetic.  
**Uses advised against** No information available

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

**Order Online At:** <https://www.spectrumchemical.com>  
**Emergency telephone number** Chemtrec 1-800-424-9300  
**Contact Person:** Tom Tyner (USA - West Coast)  
**Contact Person:** Ibad Tirmiz (USA - East Coast)

### 2. HAZARDS IDENTIFICATION

#### Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2B
Combustible dust	-

#### Label elements

##### **Warning**

**Hazard statements**  
 Harmful if swallowed

**Product code:** PR102

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 HYDROCHLORIDE, USP

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Causes skin irritation  
Causes eye irritation  
May form combustible dust concentrations in air



#### **Hazards not otherwise classified (HNOC)**

Not Applicable

#### **Other hazards**

Not available

#### **Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling  
Do not eat, drink or smoke when using this product  
Wear protective gloves  
Keep away from all ignition sources including heat, sparks, and flame  
Keep container closed and grounded  
Prevent dust accumulations to minimize explosion hazard

#### **Precautionary Statements - Response**

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  
If skin irritation occurs: Get medical advice/attention  
Take off contaminated clothing and wash it before reuse  
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell  
Rinse mouth

#### **Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

### **3. COMPOSITION/INFORMATION ON INGREDIENTS**

Component	CAS No	Weight-%
Prilocaine Hydrochloride	1786-81-8	100

### **4. FIRST AID MEASURES**

#### **First aid measures**

##### **General Advice:**

National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

##### **Skin Contact:**

Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention. If skin irritation persists, call a physician.

##### **Eye Contact:**

Flush eyes with water for 15 minutes. Get medical attention. If symptoms persist, call a physician.

##### **Inhalation:**

Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

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**Ingestion:** Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

**Most important symptoms and effects, both acute and delayed**

<b>Symptoms</b>	Causes eye irritation Causes skin irritation May cause irritation of respiratory tract Numbness of skin/eyes at site of contact Numbness and irritation of the mouth (tongue and lips) Tingling and prickling sensations Tremors Drowsiness Dizziness Ringing in the ears Blurred vision Fainting Seizures Irregular heartbeat Low blood pressure Cardiac arrest Dyspnea (Difficulty breathing and shortness of breath) May cause methemoglobinemia
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**Indication of any immediate medical attention and special treatment needed**

**Notes to Physician:** Treat symptomatically.

**Protection of first-aiders**

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

## **5. FIRE-FIGHTING MEASURES**

**Extinguishing Media**

<b>Suitable Extinguishing Media:</b>	Dry chemical. Carbon dioxide (CO <sub>2</sub> ). Water spray, mist, or foam.
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<b>Unsuitable Extinguishing Media:</b>	No information available.
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**Specific hazards arising from the chemical**

<b>Hazardous combustion products</b>	Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NO <sub>x</sub> ). Hydrogen chloride.
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<b>Specific hazards</b>	May be combustible at high temperatures. Avoid generating dust. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
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**Special Protective Actions for Firefighters**

<b>Specific Methods:</b>	No information available
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<b>Special Protective Equipment for Firefighters:</b>	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear
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## 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

**Personal Precautions:** Ensure adequate ventilation. Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep people away from and upwind of spill/leak. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition. Avoid dust formation. Avoid dispersal of dust in the air. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Non-sparking tools should be used.

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Prevent entry into waterways, sewers, basements or confined areas. Prevent product from entering drains.

### Methods and material for containment and cleaning up

**Methods for containment** Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

**Methods for cleaning up** Sweep up and shovel. Use appropriate tools to put the spilled material in a suitable chemical waste disposal container. Clean contaminated surface thoroughly.

## 7. HANDLING AND STORAGE

### Precautions for safe handling

#### **Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Keep away from incompatible materials. Minimize dust generation and accumulation. Avoid dust formation. Dry powders can build static electricity charges when subjected to friction of transfer and mixing operations. All equipment used when handling the product must be grounded. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces.

#### **Safe Handling Advice**

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Use only in well-ventilated areas. Do not breathe vapors/dust. Do not ingest. When using do not smoke. Avoid dust formation. Keep away from open flames, hot surfaces and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

### Conditions for safe storage, including any incompatibilities

#### **Technical Measures/Storage Conditions:**

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

#### **Incompatible Materials:**

Oxidizing agents

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

### **National occupational exposure limits**

#### **United States**

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Prilocaine Hydrochloride	1786-81-8	None	None	None	None

## Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Prilocaine Hydrochloride	1786-81-8	None	None	None	None

## Australia and Mexico

Component	CAS No	Australia	Mexico
Prilocaine Hydrochloride	1786-81-8	None	None

### Appropriate engineering controls

#### Engineering measures to reduce exposure:

Ensure adequate ventilation, especially in confined areas. 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. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e. there is no leakage from the equipment). It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in the handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment.

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

#### Personal Protective Equipment

<b>Eye protection:</b>	Goggles or Safety glasses with side-shields.
<b>Skin and body protection:</b>	Chemical resistant apron Gloves Long sleeved clothing
<b>Respiratory protection:</b>	Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
<b>Hygiene measures:</b>	Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical state:**  
Solid

**Appearance:**  
Crystalline powder.

**Color:**  
White.

**Odor:**  
No information available.

**Taste**  
No information available.

**Formula**  
C<sub>13</sub>H<sub>20</sub>N<sub>2</sub>O.HCl

<b>Molecular/Formula weight (g/mole):</b> 256.77 g/mol	<b>Flammability (solid, gas)</b> no data available	<b>Flashpoint (°C/°F):</b> No information available
<b>Flash Point Tested according to:</b> Not available	<b>Autoignition Temperature (°C/°F):</b> No information available	<b>Lower Explosion Limit (%):</b> No information available
<b>Upper Explosion Limit (%):</b> No information available	<b>Melting point/range(°C/°F):</b> 167-169°C/333-336°F	<b>Decomposition temperature(°C/°F):</b> No information available
<b>Boiling point/range(°C/°F):</b> No information available	<b>Bulk density:</b> 290 kg/m <sup>3</sup>	<b>Density (g/cm3):</b> No information available
<b>Specific gravity:</b> No information available	<b>pH</b> 4.7 (1%)	<b>Vapor pressure @ 20°C (kPa):</b> No information available
<b>Evaporation rate:</b> No information available	<b>Vapor density:</b> No information available	<b>VOC content (g/L):</b> No information available
<b>Odor threshold (ppm):</b> No information available	<b>Partition coefficient (n-octanol/water):</b> 2.12	<b>Viscosity:</b> No information available
<b>Miscibility:</b> No information available	<b>Solubility:</b> Freely soluble in water Freely soluble in Ethanol Insoluble in diethyl ether Slightly soluble in chloroform Very slightly soluble in Acetone	

## 10. STABILITY AND REACTIVITY

### Reactivity

Reactive with oxidizing agents

### Chemical stability

**Stability:** Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

**Conditions to avoid:** Heat. Avoid dust formation. Dust may form explosive mixture in air. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Incompatible materials.

**Incompatible Materials:** Oxidizing agents

**Hazardous decomposition products:** Hydrogen chloride. Carbon oxides. Nitrogen oxides (NOx).

### Other Information

**Corrosivity:** No information available

**Special Remarks on Corrosivity:** No information available

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

**Product code:** PR102

**Product name:** PRILOCAINE  
HYDROCHLORIDE, USP

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**Principal Routes of Exposure:**

Ingestion. Inhalation.

**Acute Toxicity****Component Information**

Prilocaine Hydrochloride	
CAS No	1786-81-8

**LD50/oral/rat** = No information available**LD50/oral/mouse** = No information available**LD50/dermal/rabbit** = No information available**LD50/dermal/rat** = No information available**LC50/inhalation/rat** = No information available**LC50/inhalation/mouse** = No information available**Other LD50 or LC50 information** = No information available**Product Information****LD50/oral/rat =****Value - Acute Tox** = No information available**LD50/oral/mouse =****Value - Acute Tox Oral** = No information available**LD50/dermal/rabbit****Value - Acute Tox** = No information available**LD50/dermal/rat****VALUE - Acute Tox Dermal** = No information available**LC50/inhalation/rat****VALUE-Vapor** = No information available**VALUE-Gas** = No information available**VALUE-Dust/Mist** = No information available**LC50/Inhalation/mouse****VALUE-Vapor** = No information available**VALUE - Gas** = No information available**VALUE - Dust/Mist** = No information available**Symptoms****Skin Contact:** Causes skin irritation. Causes local numbness (anesthetic effect).**Eye Contact:** Causes eye irritation. May cause numbness.**Inhalation** Inhalation of dust or powder may cause respiratory tract irritation. May cause other symptoms similar to those of ingestion.**Ingestion** Harmful if swallowed. May cause tingling, pricking feeling, or numbness in the extremities. May cause numbness of the mouth (lips and tongue). Ingestion may cause nausea, vomiting. May affect behavior/central nervous system (dizziness, drowsiness). May cause fainting. It may cause ringing in the ears. May cause blurred or foggy vision. May cause central nervous system depression including convulsions and unconsciousness. May affect behavior/central nervous system

(tremors, muscle twitching). May cause difficulty breathing. May cause Methemoglobinemia. May affect the cardiovascular system (hypotension). May affect cardiovascular system (hypotension, cardiac arrhythmias).

**Aspiration hazard** No information available.

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Chronic Toxicity** No information available.

**Sensitization:** May cause sensitization of susceptible persons by skin contact or by inhalation of dust.

**Mutagenic Effects:** No information available

**Carcinogenic effects:** Not considered carcinogenic.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Prilocaine Hydrochloride	1786-81-8	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

*ACGIH (American Conference of Governmental Industrial Hygienists)*

*IARC (International Agency for Research on Cancer)*

*NTP (National Toxicology Program)*

*OSHA (Occupational Safety and Health Administration of the US Department of Labor)*

**Reproductive toxicity** No data is available

**Reproductive Effects:** No information available

**Developmental Effects:** No information available

**Teratogenic Effects:** No information available

**Specific Target Organ Toxicity**

**STOT - single exposure** No information available.

**STOT - repeated exposure** No information available.

**Target Organs:** No information available.

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Ecotoxicity effects:** Aquatic environment.

*Prilocaine Hydrochloride - 1786-81-8*

**Algae/aquatic plants** 154 mg/L EC50 green algae 72h

**Fish** 188 mg/L LC50 zebra fish 96h

**Crustacea** 61 mg/L EC50 daphnia magna 48h

**Persistence and degradability:** Not readily biodegradable

**Bioaccumulative potential:** Potential for bioconcentration in aquatic organisms is low.

Mobility in soil No information available  
Other adverse effects No information available.

### 13. DISPOSAL CONSIDERATIONS

#### Disposal Methods

##### Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

##### Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Prilocaine Hydrochloride	1786-81-8	None	None	None	None

### 14. TRANSPORT INFORMATION

#### DOT

UN-No: Not Regulated  
Proper Shipping Name: No information available  
Hazard Class No information available  
Subsidiary Class No information available  
Packing group: No information available  
Emergency Response Guide Number No information available  
Marine Pollutant No data available  
DOT RQ (lbs): No information available  
Special Provisions No Information available  
Symbol(s): No information available  
Description: No information available

#### TDG (Canada)

UN-No: Not Regulated  
Proper Shipping Name: No information available  
Hazard Class No information available  
Subsidiary Risk: No information available  
Packing Group: No information available  
Marine Pollutant No Information available  
Description: No information available

#### ADR

UN Number Not regulated  
Proper Shipping Name: No information available  
Transport hazard class(es) No information available  
Packing group No information available  
Subsidiary Risk: No information available

#### IMDG

UN-No: Not Regulated  
Proper Shipping Name: No information available  
Hazard Class: No information available  
Subsidiary Risk: No information available  
Packing Group: No information available  
Marine Pollutant No information available

**RID**

**UN Number** Not Regulated  
**Proper Shipping Name:** No information available  
**Transport hazard class(es)** No information available  
**Subsidiary Risk:** No information available  
**Packing group** No information available

**ICAO (air)**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available

**IATA**

**UN Number** Not Regulated  
**Proper Shipping Name:** No information available  
**Transport hazard class(es)** No information available  
**Subsidiary Risk:** No information available  
**Packing group** No information available  
**Precautionary Statements - Response** IF exposed or concerned  
**Special Provisions** No information available

<b>15. REGULATORY INFORMATION</b>
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**International Inventories**

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia AICS	EINECS-No.
<i>Prilocaine Hydrochloride</i>	1786-81-8	Not Listed	Not present	Not present	Not present	Not listed	Present	Present 217-244-0

**U.S. Regulations****California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.****Chemicals Known to the State of California to Cause Cancer:**

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

**Chemicals Known to the State of California to Cause Reproductive Toxicity:**

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
<i>Prilocaine Hydrochloride</i>	1786-81-8	Not Listed	Not Listed	Not Listed	Not Listed

**CERCLA/SARA**

Component	CAS No	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
<i>Prilocaine Hydrochloride</i>	1786-81-8	None	None	None	None	None

## U.S. TSCA

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Prilocaine Hydrochloride	1786-81-8	Not Applicable	Not Applicable

## Canada

### WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

**Canada Hazardous Products Regulation** This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

## DSL/NDSL

Component	CAS No	Canada (DSL)	Canada (NDSL)
Prilocaine Hydrochloride	1786-81-8	Present	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Prilocaine Hydrochloride	1786-81-8	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Prilocaine Hydrochloride	1786-81-8	Not listed

## EU Classification

### EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Prilocaine Hydrochloride	1786-81-8	

### EU - CLP (1272/2008)

### R-phrases(s)

R22 - Harmful if swallowed

R36/38 - Irritating to eyes and skin

### S -phrase(s)

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

S 1/2 - Keep locked up and out of the reach of children.

S36/39 - Wear suitable protective clothing and eye/face protection

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Prilocaine Hydrochloride	1786-81-8		No information	

**The product is classified in accordance with Annex VI to Directive 67/548/EEC**

**Indication of danger:**

Xn - Harmful

Xi - Irritant

Xn



Xi

**16. OTHER INFORMATION**

**Preparation Date:** 9/18/2017  
**Revision date** 1/29/2019  
**Prepared by:** Sonia Owen

**Disclaimer:**

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

**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
PR102	Prilocaine 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

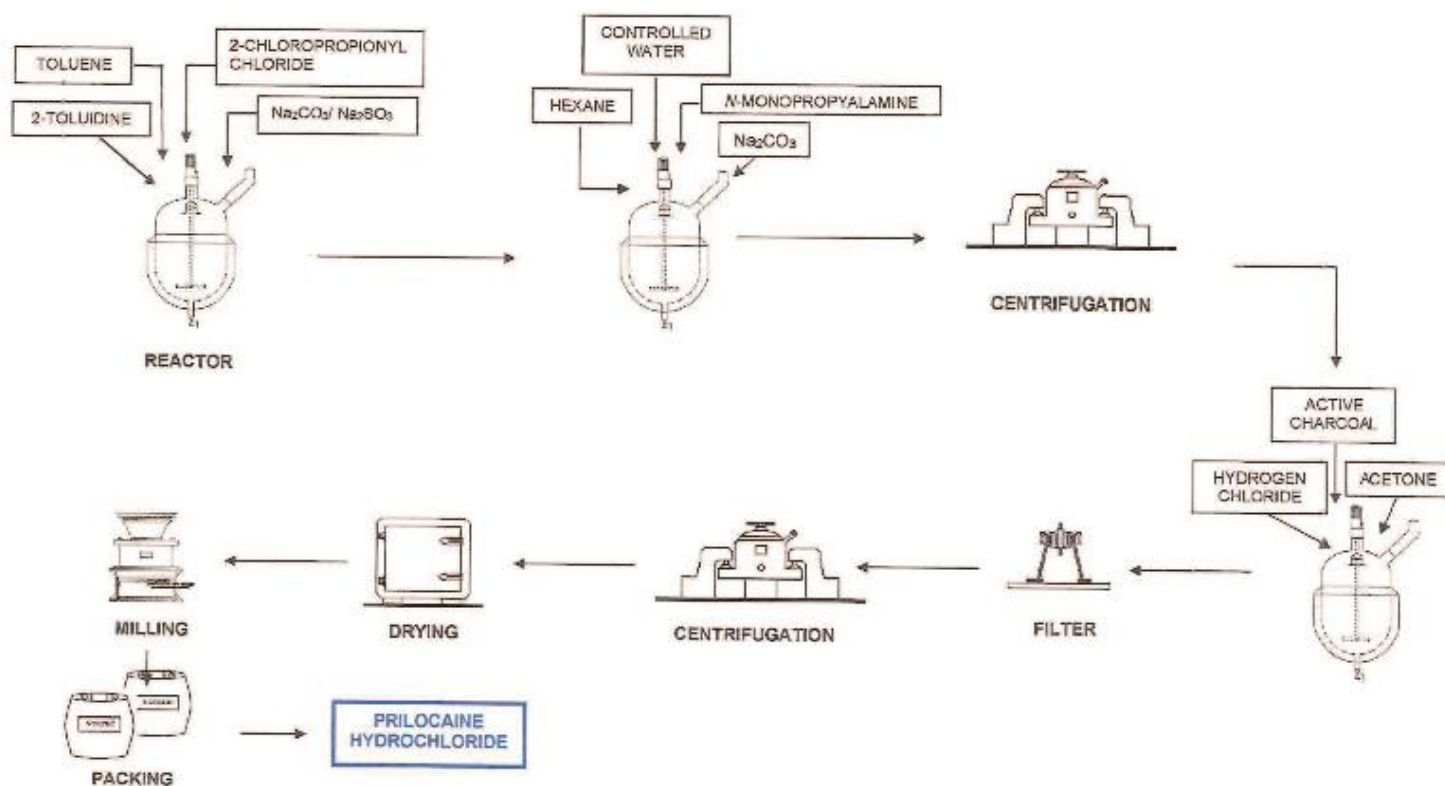
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

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 Prilocaine Hydrochloride, USP (Cat# PR102)



### CORPORATE HEADQUARTERS

769 Jersey Avenue  
New Brunswick, NJ 08901  
PHONE 732.214.1300  
FAX 732.246.7132

### WEST COAST FACILITY

14422 South San Pedro Street  
Gardena, California 90248  
PHONE 310.516.8000  
FAX 310.516.9843

## PR102, Prilocaine 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 36 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 - Prilocaine Hydrochloride, USP (Cat# PR102)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Nickel	Ni	2A	< 0.6 ppm
Palladium	Pd	2B	< 0.3 ppm
Molybdenum	Mo	3	< 45 ppm
Chromium	Cr	3	< 33 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not 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](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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

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New Brunswick, NJ 08901

PHONE 732.214.1300

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Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843



**RE: Residual Solvents - Prilocaine Hydrochloride, USP (Cat# PR102)**

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
Toluene	2	< 890 PPM
Acetone	3	< 5000 PPM

No Class 1 or 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](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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

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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.

**WARNING**

- Harmful if swallowed • Causes skin and eye irritation • May form combustible dust concentrations in air.
- Keep away from all ignition sources including heat, sparks and flame • Keep container closed and grounded • Prevent dust accumulations to minimize explosion hazard • Do not eat, drink or smoke when using this product • Wear protective gloves • Wash face, hands and any exposed skin thoroughly after handling.

**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. Take off contaminated clothing and wash it before reuse. IF skin irritation occurs: Get medical attention. IF SWALLOWED: Call a POISON CENTER or physician if you feel unwell. Rinse mouth.

**KEEP FROM CHILDREN**



**PR102                      SIZ SY**

**Prilocaine  
Hydrochloride**

USP

CAS 1786-81-8

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

**Chemical Emergency: (800)424-9300**

[www.SpectrumChemical.com](http://www.SpectrumChemical.com)

$C_{13}H_{20}N_2O \cdot HCl$                       F.W. 256.77

Manufacturer/Supplier Code ..... ?  
Manufacturer Lot Number ..... ?

Assay (Dried Basis) ..... 98.0-102.0%

MAXIMUM LIMITS

Loss on Drying ..... 0.3%  
Residue on Ignition ..... 0.1%  
Elemental Impurities ..... As reported

Organic Impurities:

Prilocaine Related Compound A .....	0.01%
Any Individual Unspecified Impurity .....	0.10%
Total Impurities .....	0.2%
Residual Solvents .....	To pass test

Keep tightly closed. Store at Room Temperature.

**WARNING:** Cancer and Reproductive Harm  
[www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)

Repackaged by Spectrum as:

G 14/J10GHS-A      ?      Lot No. XQ####

### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

769 Jersey Ave.  
New Brunswick, NJ 08901  
732.214.1300

#### West Coast Facility:

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310.516.8000