

SAFETY DATA SHEET

PRODUCT ID: PRILOCAINE HYDROCHLORIDE INJECTION

Packing Group:	Not available
Environmental Hazards:	Not available
Special Precautions for User:	Avoid temperature extremes. Prevent from freezing.

SECTION 15: REGULATORY INFORMATION

This product has been classified in accordance with the hazard criteria of the *Controlled Products Regulations* and the MSDS contains all the information required by the *Controlled Products Regulations*.

Regulatory Status:	This product is exempt from WHMIS as a drug product
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SECTION 16: OTHER INFORMATION

Name of person or group that prepared MSDS:	Novocol Pharmaceutical in conjunction with a third party consultant
Phone #:	519-623-4800
MSDS Version#:	# 4 (replaces V.3 of August 15, 2010)

Information and statements contained in this document have been obtained from manufacturers, suppliers and recognized reference sources as provided to or obtained by Novocol Pharmaceutical of Canada, Inc.

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	LD50 for Prilocaine Hydrochloride: 550 mg/kg skin-mouse
Skin Corrosion/Irritation:	May be irritating to the skin.
Serious Eye Damage/Irritation:	May be seriously irritating to the eyes. When used in gels/cream or patches, eye contact with the product has resulted in irritation sometimes leading to corneal abrasion due to loss of protective reflexes.
Respiratory or Skin Sensitization:	Not available
Interactive Effects:	Not available
Mutagenicity:	Not available
Irritancy to Product:	Not available
Carcinogenicity:	This product has not been listed as a carcinogen or a potential carcinogen by the ACGIH, the International Agency for Research on Cancer (IARC), the US National Toxicology Program (NTP) or the US Occupational Safety and Health Administration (OSHA).
Reproductive Toxicity:	In limited testing, there is no evidence at this time of impaired fertility or harm to the fetus.
Specific Target Organ Toxicity – Single Exposure:	Not available
Specific Target Organ Toxicity – Repeated Exposure:	May cause hypersensitivity. Associated with the development of methemoglobinemia.
Aspiration Hazard:	Not available. Not expected to be of concern.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity:	Not available
Persistence / Degradability:	Not available
Bioaccumulation / Accumulation:	Not available
Mobility in Environmental Media:	Not available
Other Adverse Effects:	Not available

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal:	Observe all Federal/Provincial/State and Local disposal regulations.
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SECTION 14: TRANSPORTATION INFORMATION

UN Number:	Not available
UN Proper Shipping Name:	Not available
Transport Hazard Classes:	Not available

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid
Odour and Appearance:	Clear and odourless
Odour Threshold:	Not applicable
Specific Gravity (water=1):	1
Solubility in Water	Soluble
Co-efficient of Water/Oil Distribution:	Not available
Vapour Pressure:	17 mm Hg @ 20°C
Boiling Point (°C):	100°C
Melting/Freezing Point (°C):	0°C
pH:	Not available
Vapour Density (Air=1):	0.6
Evaporation Rate (Butyl Acetate=1):	1
Flashpoint (°C) and Method:	Not flammable (water based)
Upper Flammable Limit (%):	Not available
Lower Flammable Limit (%):	Not available
Auto-ignition Temperature (°C):	Not available
Decomposition Temperature (°C):	Not available

SECTION 10: STABILITY AND REACTIVITY

Reactivity:	Stable
Chemical Stability:	Stable
Conditions to Avoid:	None
Incompatible Materials:	Incompatible with compounds which react violently with water
Hazardous Decomposition Products:	None

SECTION 11: TOXICOLOGICAL INFORMATION

Route of Entry:	<input checked="" type="checkbox"/> Skin Contact <input checked="" type="checkbox"/> Skin Absorption <input checked="" type="checkbox"/> Eye Contact <input checked="" type="checkbox"/> Inhalation <input checked="" type="checkbox"/> Ingestion
Acute Toxicity:	Not expected to be acutely toxic. Acute measures of toxicity (i.e. LD50 and LC50) are not available for this mixture.

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Environmental precautions:	Prevent spills from entering sewers and watercourses. Cover drains.
Methods and materials for containment and cleaning up:	Clean up spills with normal procedures used for non-hazardous liquids. This can include: absorb spill with inert material, then place in a chemical waste container. Clean surface thoroughly with water to remove residual contamination.

SECTION 7: HANDLING AND STORAGE

Handling Procedures and Equipment:	Caution should be used to prevent against ingestion and contact with eyes. Handle with care to avoid breakage.
Storage Requirements:	Store in a cool, dry place. Avoid extremes in temperature.
Packaging:	USP Type 1 glass with rubber stopper and cap
Sensitivity to Mechanical Impact:	No
Sensitivity to Static Discharge:	No

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:	Chemical Agent	Occupational Exposure Limits (OEL)			
		ACGIH ^a		Ontario	
		TWA ^b	STEL ^c	TWA ^b	STEL ^c
	Prilocaine Hydrochloride	Not available	Not available	Not available	Not available

a – American Conference of Governmental Industrial Hygienists

b – Time Weighted Average

c - Short-term Exposure Limit

Personal Protective Equipment (PPE):	
Gloves (specify):	Not normally required
Respiratory (specify):	Not normally required
Eye (specify):	If potential for contact with eyes exists, wear safety glasses with side shields.
Footwear (specify):	Not normally required
Other Equipment (specify):	RESUSCITATIVE EQUIPMENT AND DRUGS SHOULD BE AVAILABLE DURING DENTAL PROCEDURES
Engineering Controls (e.g. ventilation, enclosed process, specify):	Not normally required

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	rinsing P312 – Call a POISON CENTER or doctor/physician Storage P405 – Store locked up Disposal P501 – Dispose of contents/container in accordance with local/provincial/federal regulations
WHMIS Regulatory Status:	Not WHMIS-Controlled

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Identity	Concentration (Percent weight/weight)	CAS Number
Prilocaine Hydrochloride	4	1786-81-8

SECTION 4: FIRST AID MEASURES

Inhalation:	Remove patient from exposure.
Eye Contact:	Immediately flush eyes with plenty of water for at least 15 minutes while holding eyelids open. Rinse continuously while on way to get medical attention.
Skin Contact:	Remove contaminated clothing. Wash skin with soap and water
Ingestion:	Get immediate medical attention. Do not induce vomiting unless instructed to do so by poison control or physician.
Personal Protective Equipment for First Aid Responders:	Wear impermeable gloves to avoid skin contact (e.g. nitrile, natural rubber).

SECTION 5: FIRE FIGHTING MEASURES

Suitable extinguishing media:	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials
Hazardous Combustion Products:	Not available
Special Protective Actions for Firefighters:	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions:	Caution should be used to prevent against ingestion and contact with eyes. Wear safety glasses with side shields.
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SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Prilocaine Hydrochloride USP, 4% Injection
Brand Name:	CITANEST® PLAIN DENTAL (prilocaine hydrochloride injection, USP)
Manufacturer / Supplier:	DENTSPLY Pharmaceutical 1301 Smile Way York, PA, USA 1-800-989-8825 http://www.dentsply.com
Prepared By:	Novocol Pharmaceutical in conjunction with a third party consultant
Emergency Phone Number:	1-416-522-3854
Product Use:	Local anesthetic solution for use in peripheral nerve blocks
Date of Preparation:	July 19, 2013

SECTION 2: HAZARDS IDENTIFICATION

Classification:	Narcotic effects, Category 3
GHS Label Symbol:	
Hazard Statements:	<p>Warning</p> <p>H336 - May cause drowsiness or dizziness May cause skin and/or serious eye irritation Causes central nervous system effects such as drowsiness, confusion, excitability and nervousness. Acts as a depressant on the cardiovascular system.</p> <p>Avoid use in individuals with hypersensitivities to amide-type anesthetics. Use with caution in individuals with diabetes and/or severe hypertension.</p> <p>CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOLOGICAL INFORMATION</p> <p>Signs and Symptoms of Overexposure: Drowsiness, confusion, excitability, nervousness, drop in blood pressure, fatigue, bluish discoloration of fingernails, lips, or skin, difficulties in breathing.</p>
Precautionary Statements:	<p>Prevention</p> <p>P261 – Do not breathe mist/vapours/spray P271 – Use in a well-ventilated area P280 – Wear eye protection</p> <p>Response</p> <p>P304+P430 – If inhaled – remove victim to fresh air and keep at rest in a position comfortable for breathing P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue</p>