


SAFETY DATA SHEET

PRODUCT ID: PRILOCAINE HYDROCHLORIDE INJECTION

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>

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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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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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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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	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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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)

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