

MATERIAL SAFETY DATA SHEET

PRODUCT ID: PRILOCAINE HYDROCHLORIDE INJECTION

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

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|--------------------------|--|
| 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: | August 15, 2010 |

SECTION 2: HAZARDS IDENTIFICATION

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|----------------------------------|--|
| Emergency Overview: | Clear, odourless liquid May cause severe eye irritation and permanent damage Causes central nervous system effects such as drowsiness, confusion, excitability and nervousness. Acts as a depressant on the cardiovascular system. Avoid use in individuals with hypersensitivities to amide-type anesthetics. Use with caution in individuals with diabetes and/or severe hypertension. |
| WHMIS Regulatory Status: | Not WHMIS-Controlled |
| Potential Health Effects: | Routes of Exposure: eye, skin, ingestion Eye: May cause severe irritation, permanent damage, allergic reaction Skin: May cause irritation, allergic reaction Ingestion: May cause irritation, allergic reaction Chronic Effects: May cause hypersensitivity. Associated with the development of methemoglobinemia. Signs and Symptoms of Overexposure: Drowsiness, confusion, excitability, nervousness, drop in blood pressure, fatigue, bluish discoloration of fingernails, lips, or skin, difficulties in breathing. CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOPIAL INFORMATION |
| Potential Environmental Effects: | Not available |

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SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

| Chemical Identity | Concentration (Percent weight/weight) | CAS Number | LD ₅₀ | LC ₅₀ |
|--------------------------|--|------------|----------------------|------------------|
| Prilocaine Hydrochloride | 4 | 1786-81-8 | 550 mg/kg skin mouse | Not available |

SECTION 4: FIRST AID MEASURES

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|---------------|---|
| 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. |

SECTION 5: FIRE FIGHTING MEASURES

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| Conditions of Flammability: | Not flammable |
| Means of Extinction: | Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials |
| Sensitivity to Mechanical Impact: | No |
| Sensitivity to Static Discharge: | No |
| 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

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| Leak and Spill Procedure: | 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. |
| Other Information: | Caution should be used to prevent against ingestion and contact with eyes. Wear safety glasses with sideshields. |

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SECTION 7: HANDLING AND STORAGE

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| 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 cartridge with rubber stopper and cap |

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 |

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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|---|---------------------|
| 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 |

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|-------------------------------------|-----------------------------|
| 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 |

SECTION 10: STABILITY AND REACTIVITY

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|-----------------------------------|--|
| Stability: | Stable |
| Incompatible Materials: | Incompatible with compounds which react violently with water |
| Conditions of Reactivity: | None |
| Hazardous Decomposition Products: | None |

SECTION 11: TOXICOLOGICAL INFORMATION

| | |
|-------------------------|---|
| Route of Entry: | <input checked="" type="checkbox"/> Skin Contact <input type="checkbox"/> Skin Absorption <input checked="" type="checkbox"/> Eye Contact <input type="checkbox"/> Inhalation <input checked="" type="checkbox"/> Ingestion |
| Irritancy to Product: | Not available |
| Synergistic Products: | 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. |
| Teratogenicity: | In limited testing, there is no evidence at this time of harm to the fetus. |
| Mutagenicity: | Not available |
| Sensitivity to Product: | Not available |

SECTION 12: ECOLOGICAL INFORMATION

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|---------------------------------|---------------|
| Ecotoxicity: | Not available |
| Persistence / Degradability: | Not available |
| Bioaccumulation / Accumulation: | Not available |

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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

SECTION 14: TRANSPORTATION INFORMATION

Basic Shipping Description: Not available

Additional Information: Not available

Special Precautions: 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

SECTION 16: OTHER INFORMATION

Name of person or group that prepared MSDS: Environmental Health & Safety

Phone #: 519-623-4800

MSDS Version#: # 3 (replaces V.2 of March 9, 2007)

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