

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: | Not Available |
| Manufacturer / Supplier: | Septodont 25 Wolseley Court Cambridge, Ontario, Canada N1R 6X3 519-623-4800 http://www.septodont.com/ |
| Prepared By: | Septodont in conjunction with a third party consultant |
| Emergency Phone Number: | (519) 623-4800 (Monday-Friday 08:30 to 16:30 EST) |
| Product Use: | Local anesthetic solution for use in peripheral nerve blocks |
| Date of Preparation: | July 11, 2016 |

SECTION 2: HAZARDS IDENTIFICATION

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| Classification: | This product is exempt from WHMIS 2015 as a drug product. Information provided is for worker education and training purposes. <u>Equivalent</u> Class: Specific Target Organ Toxicity – Single Exposure: Narcotic effects, Category 3 |
| <u>Equivalent</u> GHS Label Symbol: |  |
| Hazard Statements: | Warning 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. Avoid use in individuals with hypersensitivities to amide-type anesthetics. Use with caution in individuals with diabetes and/or severe hypertension. CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOLOGICAL INFORMATION Signs and Symptoms of Overexposure: Drowsiness, confusion, excitability, nervousness, drop in blood pressure, fatigue, bluish discoloration of fingernails, lips, or skin, difficulties in breathing. |
| Precautionary Statements: | Prevention P261 – Do not breathe mist/vapours/spray P271 – Use in a well-ventilated area P280 – Wear eye protection Response |

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| | <p>P304+P430 – If inhaled – remove victim to fresh air and keep at rest in a position comfortable for breathing</p> <p>P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing</p> <p>P312 – Call a POISON CENTER or doctor/physician</p> <p>Storage</p> <p>P405 – Store locked up</p> <p>Disposal</p> <p>P501 – Dispose of contents/container in accordance with local/provincial/federal regulations</p> |
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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

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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. |
| Personal Protective Equipment for First Aid Responders: | Wear impermeable gloves to avoid skin contact (e.g. nitrile, natural rubber). |

SECTION 5: FIRE FIGHTING MEASURES

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| 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. |

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SECTION 6: ACCIDENTAL RELEASE MEASURES

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| Personal precautions: | Caution should be used to prevent against ingestion and contact with eyes. Wear safety glasses with side shields. |
| 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

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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 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

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| 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 |

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| Engineering Controls (e.g. ventilation, enclosed process, specify): | Not normally required |
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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 |
| 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

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| 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

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| 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 |
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| Acute Toxicity: | Not expected to be acutely toxic. Acute measures of toxicity (i.e. LD50 and LC50) are not available for this mixture. 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: | Causes central nervous system effects such as drowsiness, confusion, excitability and nervousness. Acts as a depressant on the cardiovascular system. |
| 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

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| 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

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

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| UN Number: | Not available |
| UN Proper Shipping Name: | Not available |
| Transport Hazard Classes: | Not available |
| Packing Group: | Not available |
| Environmental Hazards: | Not available |
| Special Precautions for User: | Avoid temperature extremes. Prevent from freezing. |

SECTION 15: REGULATORY INFORMATION

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

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| Name of person or group that prepared SDS: | Septodont in conjunction with a third party consultant |
| Phone #: | 519-623-4800 |
| SDS Version#: | # 5 (replaces V.4 of July 19, 2013) |

Information and statements contained in this document have been obtained from manufacturers, suppliers and recognized reference sources as provided to or obtained by Septodont.

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