

SAFETY DATA SHEET

PRODUCT ID: PHENTOLAMINE MESYLATE INJECTION

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

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| Product Name: | Phentolamine Mesylate Injection, 0.235 mg/mL |
| Brand Name: | OraVerse™ (phentolamine mesylate) Injection |
| 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: | Adrenergic blocker used to reverse the effects of local anesthesia. |
| 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. Not classifiable according to GHS |
| GHS Label Symbol: | None |
| Hazard Statements: | May cause skin and/or eye irritation Can cause central nervous system effects such as dizziness and weakness. Stimulates the gastrointestinal tract, potentially resulting in gastric secretion, nausea, vomiting, diarrhea. Acts as a depressant (by vasodilation) on the cardiovascular system, with potential effects including hypotension (lowering of blood pressure), tachycardia (abnormal heart rhythm). Avoid exposure to individuals with hypersensitivity to phentolamine. CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOLOGICAL INFORMATION Signs and Symptoms of Overexposure: Drop in blood pressure, tachycardia, cardiac stimulation, dizziness, excitability, headache. |
| Precautionary Statements: | Response P312 – Call a POISON CENTER or doctor/physician if you feel unwell Disposal P501 – Dispose of contents/container in accordance with local/provincial/federal regulations |

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SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

| Chemical Identity | Concentration (Percent weight/weight) | CAS Number |
|---|--|------------|
| Phentolamine mesylate | 0.0235 | 65-28-1 |
| d-Mannitol | 5 | 69-65-8 |
| Sodium acetate | 0.136 | 127-09-3 |
| Ethylenediaminetetraacetic acid-Na ₂ | 0.05 | 139-33-3 |

SECTION 4: FIRST AID MEASURES

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| Inhalation: | Remove person from exposure. |
| Eye Contact: | Flush eyes with plenty of water for at least 15 minutes while holding eyelids open. Get medical attention, if irritation persists. |
| Skin Contact: | Wash skin with soap and water |
| Ingestion: | Flush mouth with water and get immediate medical attention. Induce vomiting only if patient is conscious. Never attempt to induce vomiting in an unconscious person. |
| Injection: | Get immediate medical attention. |
| 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. |

SECTION 6: ACCIDENTAL RELEASE MEASURES

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| Personal precautions: | Take precautions to avoid skin (i.e. protective gloves, long sleeves, etc.) and eye contact (i.e. wear safety glasses with side shields) and ingestion. |
| Environmental precautions: | Prevent spills from entering sewers and watercourses. Cover drains. |

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| 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. |
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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 skin and eyes. Handle with care to avoid breakage. |
| Storage Requirements: | Store between 20-25°C (68-77°F). Excursions of 15-30°C (59-86°F) are permitted. Protect from direct heat and light. Do not permit to freeze. |
| Packaging: | Glass dental cartridges designed to deliver 1.7 mL of solution per cartridge |
| 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 |
| | Phentolamine Mesylate | Not available | Not available | Not available | Not available |
| | d-Mannitol | Not available | Not available | Not available | Not available |
| | Sodium Acetate | Not available | Not available | Not available | Not available |
| | Ethylenediamine tetraacetic acid-Na ₂ | 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 but be prepared to wear impervious gloves if container breakage and therefore contact with product may occur. |
| 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 |
| Clothing (specify): | Wear clothing to prevent skin contact, as necessary (e.g. lab coat with closed front and sleeves). |

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| Other Equipment (specify): | Not normally required |
| 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, colourless solution |
| Odour Threshold: | Not available |
| Specific Gravity (water=1): | Not available |
| Solubility in Water | Soluble |
| Co-efficient of Water/Oil Distribution: | Not available |
| Vapour Pressure: | Not available |
| Percent Volatile: | 0% |
| Boiling Point (°C): | Not available |
| Melting/Freezing Point (°C): | Not available |
| pH: | 4.0 |
| Vapour Density (Air=1): | Not available |
| Evaporation Rate (Butyl Acetate=1): | Not available |
| 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 |

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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 |
| Acute Toxicity: | <p>Not expected to be acutely toxic.</p> <p>Acute measures of toxicity (i.e. LD50 and LC50) are not available for this mixture.</p> <p>LD50s for Phentolamine Mesylate: 1250 mg/kg oral-rat; 1100 mg/kg oral-mouse; No Observed Adverse Effect Level (NOAEL) 75 mg/kg oral-rat</p> <p>LD50s for d-Mannitol: 13,500 mg/kg oral-rat; 22,000 mg/kg oral-mouse</p> <p>LD50 for Sodium Acetate: 3,500 mg/kg oral-rat; 6,900 mg/kg oral-mouse; LC50 greater than 30/mg/L rat</p> <p>LD50 for Ethylenediaminetetraacetic acid-Na₂: 2000 mg/kg oral-rat; 2050 mg/kg oral-mouse</p> |
| Skin Corrosion/Irritation: | May be irritating to the skin. |
| Serious Eye Damage/Irritation: | May be irritating to the eyes. |
| Respiratory or Skin Sensitization: | Not available |
| Interactive Effects: | Not available |
| Mutagenicity: | Not mutagenic in the Ames assay. |
| Carcinogenicity: | <p>This product and its ingredients have 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).</p> <p>A published report of a single two-year rat carcinogenicity study of orally administered phentolamine mesylate stated that chronic treatment with doses of 10, 50 and 150 mg/kg reduced survival and induced the development of hibernomas in a non dose-related fashion. The frequencies of pituitary gland and liver adenomas were statistically increased in treated rats but the compound is not listed as a known carcinogen.</p> |
| Reproductive Toxicity: | No evidence of impaired fertility was observed in male rats at doses up to 150 mg/kg. No evidence of teratogenic effects. |
| Specific Target Organ Toxicity – Single Exposure: | Not available |
| Specific Target Organ Toxicity – Repeated Exposure: | Not available |
| Aspiration Hazard: | Not available. Not expected to be of concern. |

SECTION 12: ECOLOGICAL INFORMATION

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| Ecotoxicity: | Not available |
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| 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: | Phentolamine mesylate is not a DOT hazardous substance according to 49 CFR 172.101. Phentolamine mesylate is not a Marine Pollutant. |
| Special Precautions for User: | Avoid temperature extremes. Prevent from freezing. |

SECTION 15: REGULATORY INFORMATION

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| OSHA Regulatory Status: | Phentolamine mesylate is not listed as a hazardous product in the SARA, RCRA and CERCLA regulations. |
| Regulatory Status: | This product is exempt from current WHMIS legislation as a drug product |

SECTION 16: OTHER INFORMATION

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| <ol style="list-style-type: none"> 1. This SDS does not address therapeutic use of this material. 2. Use of this product should be through the direction of a dentist. 3. Persons administering this drug to patients must be careful to avoid needle sticks from syringes used in the administration. All needle sticks must be reported to your management. | |
| 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) |

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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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