

# SAFETY DATA SHEET

**PRODUCT ID: PHENTOLAMINE MESYLATE INJECTION**

## SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Phentolamine Mesylate Injection, 0.235 mg/mL
Brand Name:	<b>OraVerse™</b> (phentolamine mesylate) Injection
Manufacturer / Supplier:	Septodont 25 Wolseley Court Cambridge, Ontario, Canada N1R 6X3 519-623-4800 <a href="http://www.septodont.com/">http://www.septodont.com/</a>
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

Classification:	<b>This product is exempt from WHMIS 2015 as a drug product. Information provided is for worker education and training purposes.</b> 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. <b>CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOLOGICAL INFORMATION</b> Signs and Symptoms of Overexposure: Drop in blood pressure, tachycardia, cardiac stimulation, dizziness, excitability, headache.
Precautionary Statements:	<b>Response</b> P312 – Call a POISON CENTER or doctor/physician if you feel unwell <b>Disposal</b> 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 <sub>2</sub>	0.05	139-33-3

## SECTION 4: FIRST AID MEASURES

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

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:	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

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 <sup>a</sup>		Ontario	
		TWA <sup>b</sup>	STEL <sup>c</sup>	TWA <sup>b</sup>	STEL <sup>c</sup>
	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 <sub>2</sub>	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 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

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

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

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-Na<sub>2</sub>: 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

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

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
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

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

<ol style="list-style-type: none"> <li>This SDS does not address therapeutic use of this material.</li> <li>Use of this product should be through the direction of a dentist.</li> <li>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.</li> </ol>	
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.*

*Septodont believes the information to be reliable but expressly disclaims any liability for providing such information and toxicology to our customers.*