

MATERIAL 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:	OraVerse ™ (phentolamine mesylate) Injection
Manufacturer / Supplier:	Novocol Pharmaceutical of Canada, Inc. P. O. Box 68 Cambridge, Ontario, Canada N1R 5S9 519-623-4800 http://www.septodont.ca/
Prepared By:	Novocol Pharmaceutical in conjunction with a third party consultant
Emergency Phone Number:	1-800-535-5053
Product Use:	Adrenergic blocker used to reverse the effects of local anesthesia.
Date of Preparation:	May 31, 2011

SECTION 2: HAZARDS IDENTIFICATION

Emergency Overview:	Clear, odourless liquid May cause eye and skin 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.
WHMIS Regulatory Status:	Not WHMIS-Controlled
Potential Health Effects:	Routes of Exposure: eye, skin, ingestion Eye: May cause irritation Skin: May cause irritation Ingestion: May cause irritation Chronic Effects: Not available Signs and Symptoms of Overexposure: Drop in blood pressure, tachycardia, cardiac stimulation, dizziness, excitability, headache. CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOLOGICAL 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
Phentolamine mesylate	0.0235	1722-62-9	1250 mg/kg oral-rat 1100 mg/kg oral-mouse NOAEL* 75 mg/kg oral-rat	Not available
d-Mannitol	5	69-65-8	13,500 mg/kg oral-rat 22,000 mg/kg oral-mouse	Not available
Sodium acetate	0.136	127-09-3	3,500 mg/kg oral-rat 6,900 mg/kg oral-mouse	Greater than 30/mg/L rat
Ethylenediaminetetraacetic acid-Na ₂	0.05	139-33-3	2000 mg/kg oral-rat 2050 mg/kg oral-mouse	Not available

*NOAEL= No Observed Adverse Effect Level

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.

SECTION 5: FIRE FIGHTING MEASURES

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

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SECTION 6: ACCIDENTAL RELEASE MEASURES

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.
Environmental Precautions:	Avoid drain disposal. Refer to local water authority.
Other Information:	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.

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

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

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

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	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).
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

SECTION 10: STABILITY AND REACTIVITY

Stability:	Stable
Incompatible Materials:	Incompatible with compounds which react violently with water
Conditions of Reactivity:	Not available
Hazardous Decomposition Products:	Not available

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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:	May be irritating to eyes and skin.
Synergistic Products:	Not available
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.
Teratogenicity:	No evidence of teratogenic effects.
Mutagenicity:	Not mutagenic in the Ames assay.
Sensitivity to Product:	Not available

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

Basic Shipping Description:	Not available
Additional Information:	Phentolamine mesylate is not a DOT hazardous substance according to 49 CFR 172.101.

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	Phentolamine mesylate is not a Marine Pollutant.
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
SARA 313 Listed?:	Not listed
CERCLA Listed?:	Not listed
RCRA Listed?:	Not listed

SECTION 16: OTHER INFORMATION

1. This MSDS 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 MSDS:	Novocol Pharmaceutical in conjunction with a third party consultant
Phone #:	519-623-4800
MSDS Version#:	# 3 (replaces V.2 of December 1, 2008)

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