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## MATERIAL SAFETY DATA SHEET

Product: Phentolamine mesylate Injection  
Brand Name: OraVerse™ (phentolamine mesylate) Injection

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### SECTION 1 - GENERAL INFORMATION

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**MANUFACTURER:** Novocol Pharmaceutical of Canada, Inc.  
P.O. Box 68  
Cambridge, ON, Canada  
N1R 5S9

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### SECTION 2 – COMPOSITION INFORMATION

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Component	CAS #	OSHA PEL	ACGIH TLV	Other Recommended Limits
Phentolamine mesylate	65-28-1	Not Listed	Not Listed	Not Listed
Na <sub>2</sub> -EDTA	60-00-4	Not Listed	Not Listed	Not Listed
D-Mannitol	69-65-8	Not Listed	Not Listed	Not Listed

OraVerse™ is a sterile aqueous formulation for injection containing phentolamine mesylate, USP at a concentration of 0.235 mg/mL. OraVerse™ is supplied in glass dental cartridges designed to deliver 1.7 mL of solution per cartridge.

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### SECTION 3 – HEALTH HAZARD DATA

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**Routes of Entry:** Exposure may occur via ingestion, eye contact or skin contact.

**Health Hazards:** Avoid ingestion and systemic absorption. Avoid contact with eyes or skin. Phentolamine is an adrenergic blocker; target organs include circulatory, digestive and central nervous system.

**Carcinogenicity:** *NTP:* No; *IARC Monographs:* None; *OSHA Regulated:* No

**Signs & Symptoms of Exposure:** Irritation to eyes and skin.

**Medical Conditions:** Avoid use in individuals with hypersensitivity to phentolamine. CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOLOGICAL INFORMATION.

## SECTION 4 – FIRST AID MEASURES

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**Eye Exposure:** Immediately flush thoroughly with water for at least 15 minutes.  
**Skin Exposure:** Wash thoroughly with soap and water.  
**Ingestion:** Flush mouth with water and seek medical attention immediately. If person is conscious, induce vomiting and seek immediate medical attention. Never induce vomiting in an unconscious person.

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## SECTION 5 – FIRE AND EXPLOSION HAZARD DATA

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**Flash Point:** N/A; Product is liquid  
**Flammable Limits:** N/A; Product is liquid  
**Extinguishing Media:** N/A; Product is liquid  
**Special Fire Fighting Procedures:** None  
**Unusual Fire/Explosion Hazards:** None

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## SECTION 6 – ACCIDENTAL RELEASE INFORMATION

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**Release to Land:** Clean up spills with normal procedures used for non-hazardous liquids.  
**Release to Air:** N/A; Product is liquid  
**Release to Water:** Refer to local water authority; Avoid drain disposal.

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## SECTION 7 – PRECAUTIONS FOR SAFE HANDLING AND USE

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**Steps to Take in Case of Spill:** See Section 6 above; Absorb spill with inert material, then place in chemical waste container. Clean surface with water to remove residual contamination.  
**Waste Disposal Method:** Dispose as a non-hazardous waste.  
**Precautions When Handling/Storing:** Store at 20-25°C (68-77°F) [See USP Controlled Room Temperature]; excursions of 15-30°C (59-86°F) are permitted. Protect from direct heat and light. Do not permit to freeze. Handle with care to avoid breakage.  
**Other Precautions:** Caution against ingestion and contact with eyes or skin is recommended.

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## SECTION 8 – CONTROL MEASURES AND PERSONAL PROTECTION EQUIPMENT

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**Respiratory Protection:** None required under normal conditions of use.  
**Ventilation:** None required under normal conditions of use.

**Protective Gloves:** None normally required; recommended for cleanup of spills.  
**Eye Protection:** Goggles/safety glasses recommended as a precaution.  
**Other Protective Equipment:** Necessary clothing to prevent skin contact, such as a lab coat with a closed front and sleeves.

RESUSCITATIVE EQUIPMENT AND DRUGS SHOULD BE AVAILABLE DURING DENTAL PROCEDURES.

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## SECTION 9 – PHYSICAL AND CHEMICAL CHARACTERISTICS

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<b>Appearance:</b>	Clear colorless solution
<b>Boiling Point:</b>	Unknown
<b>Melting Point:</b>	Not applicable
<b>Specific Gravity (H<sub>2</sub>O =1):</b>	Unknown
<b>Vapor Pressure:</b>	Unknown
<b>Percent Volatile:</b>	0%
<b>Vapor Density (Air=1):</b>	Unknown
<b>Evaporation Rate (Butyl Acetate =1):</b>	Unknown
<b>Solubility in Water:</b>	Soluble
<b>pH:</b>	4.0

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## SECTION 10 – STABILITY AND REACTIVITY DATA

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<b>Stability:</b>	Stable
<b>Reactivity Data:</b>	Unknown
<b>Incompatibility:</b>	Unknown
<b>Hazardous Decomposition:</b>	Unknown
<b>Hazardous Polymerization:</b>	Unknown
<b>Conditions to Avoid:</b>	None known

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## SECTION 11 – TOXICOLOGICAL INFORMATION

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**Toxicity data for phentolamine mesylate (active ingredient):**

<b>Carcinogenicity:</b> Not considered a carcinogen	<b>Teratogenic effects:</b> Non-teratogenic
<b>Mutagenicity:</b> Non-mutagenic	<b>Genotoxicity:</b> Non-genotoxic
<b>LD<sub>50</sub> (oral-rats):</b> 1250 mg/kg	<b>LD<sub>50</sub> (oral-mice):</b> 1100 mg/kg
<b>NOAEL (oral, rats):</b> 75 mg/kg	

Additional reproductive health data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS)

The active ingredient of OraVerse™, phentolamine mesylate, is a well established vasodilator approved for use in humans. The intraoral administration of OraVerse™ was investigated in dogs and found to be well-tolerated at clinical doses. Oral administration of phentolamine mesylate to rats and mice resulted in LD<sub>50</sub> values of 1250 mg/kg and 1100 mg/kg, respectively. A male reproductive study of oral phentolamine mesylate in rats showed no mating or fertility problems with doses as high as 150 mg/kg. Phentolamine and related impurities in the OraVerse™ were found to be non-mutagenic and non-genotoxic.

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.

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## **SECTION 12 – ENVIRONMENTAL IMPACT INFORMATION**

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Information is currently not available on the environmental impact of phentolamine mesylate. Handle in a manner to prevent spills or releases to the environment.

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## **SECTION 13 – DISPOSAL INFORMATION**

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Dispose of via incineration at an approved/permitted waste disposal facility according to federal, state and local guidelines.

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## **SECTION 14 – TRANSPORTATION INFORMATION**

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Phentolamine mesylate is not a DOT hazardous substance according to 49 CFR 172.101. Phentolamine mesylate is not a Marine Pollutant.

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## **SECTION 15 – REGULATORY INFORMATION**

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SARA 313 Listed?: No  
CERCLA Listed?: No  
RCRA Listed?: No

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## SECTION 16 – OTHER INFORMATION

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1. Use of this product should be through the direction of a dentist. This MSDS does not address therapeutic use of this material.
2. 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.

This information is believed to be accurate but does not purport to be all inclusive. It is intended for use by persons having the necessary technical skill. Novalar Pharmaceuticals, Inc. and Novocol Pharmaceutical of Canada, Inc. shall not be held liable for any damage resulting from the use or reliance on this information or from contact or handling the above product.