

# MATERIAL SAFETY DATA SHEET

**PRODUCT ID: BUPIVACAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION**

## SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Bupivacaine Hydrochloride and Epinephrine Injection
Brand Name:	<b>VIVACAINE®</b> (Bupivacaine Hydrochloride 0.5% and Epinephrine 1:200,000; Injection)
Manufacturer / Supplier:	Novocol Pharmaceutical of Canada, Inc. P. O. Box 68 Cambridge, Ontario, Canada N1R 5S9 519-623-4800 <a href="http://www.septodont.ca/">http://www.septodont.ca/</a>
Prepared By:	Novocol Pharmaceutical in conjunction with a third party consultant
Emergency Phone Number:	1-800-647-0643 (please follow prompts)
Product Use:	Local anesthetic solution for use in peripheral nerve blocks
Date of Preparation:	August 15, 2010

## SECTION 2: HAZARDS IDENTIFICATION

Emergency Overview:	Clear, odourless liquid Highly toxic by ingestion. May cause 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.
WHMIS Regulatory Status:	Not WHMIS-Controlled
Potential Health Effects:	Routes of Exposure: eye, skin, ingestion Eye: May cause irritation, allergic reaction Skin: May cause irritation, allergic reaction Ingestion: Highly toxic; may cause irritation, allergic reaction Chronic Effects: May cause hypersensitivity Signs and Symptoms of Overexposure: Drowsiness, confusion, excitability, nervousness, drop in blood pressure, fatigue, bluish discoloration of fingernails, lips, or skin, difficulties in breathing. 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 <sub>50</sub>	LC <sub>50</sub>
Bupivacaine Hydrochloride	0.5	73360-54-0	18 mg/kg oral rabbit	Not available
Epinephrine	0.0005	51-43-4	5 mg/kg dermal rat	Not available

## SECTION 4: FIRST AID MEASURES

Inhalation:	Remove patient 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:	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.

## 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

## 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.
Other Information:	Caution against ingestion and contact with eyes is recommended. Wear safety glasses with sideshields.

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## SECTION 7: HANDLING AND STORAGE

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 cartridge with rubber stopper and cap

## 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>
	Articaine Hydrochloride	Not available	Not available	Not available	Not available
	Epinephrine	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				
Respiratory (specify):	Not normally required				
Eye (specify):	Not normally required				
Footwear (specify):	Not normally required				
Other Equipment (specify):	RESUSCITATIVE EQUIPMENT AND DRUGS SHOULD BE AVAILABLE DURING DENTAL PROCEDURES				
Engineering Controls (e.g. ventilation, enclosed process, specify):	Not normally required				

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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

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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

## SECTION 10: STABILITY AND REACTIVITY

Stability:	Stable
Incompatible Materials:	Incompatible with compounds which react violently with water
Conditions of Reactivity:	None
Hazardous Decomposition Products:	None

## 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:	Not available
Synergistic Products:	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:	Not available
Teratogenicity:	Animal studies have reported decreased survival rates of pups at levels 5 and 9 times the maximum recommended daily human dose.
Mutagenicity:	Not available
Sensitivity to Product:	Not available

## SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity:	Not available
Persistence / Degradability:	Not available
Bioaccumulation / Accumulation:	Not available

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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.

## SECTION 14: TRANSPORTATION INFORMATION

Basic Shipping Description: Not available

Additional Information: Not available

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*.

OSHA Regulatory Status: Epinephrine is listed as a hazardous product in the RCRA (EPA) and CERCLA (EPA) regulations.

Regulatory Status: This product is exempt from WHMIS as a drug product

## SECTION 16: OTHER INFORMATION

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 March 9, 2007)

*Information and statements contained in this document have been obtained from manufacturers, suppliers and recognized reference sources as provided to or obtained by Novocol Pharmaceutical of Canada, Inc.*

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