


# 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) <b>SURGICAINE™</b> (Bupivacaine Hydrochloride 0.5% and Epinephrine 1:200,000; 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:	Local anesthetic solution for use in peripheral nerve blocks
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> Equivalent Class: Specific Target Organ Toxicity – Single Exposure: Narcotic effects, Category 3 Acute Toxicity, Category 5
Equivalent GHS Label Symbol:	
Hazard Statements:	<b>Warning</b> H336 - May cause drowsiness or dizziness H303 - May be harmful if swallowed May cause skin and/or 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. <b>CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOPOLIAL INFORMATION</b>

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	Signs and Symptoms of Overexposure: Drowsiness, confusion, excitability, nervousness, drop in blood pressure, fatigue, bluish discoloration of fingernails, lips, or skin, difficulties in breathing.
Precautionary Statements:	<p><b>Prevention</b>            P261 – Do not breathe mist/vapours/spray            P271 – Use in a well-ventilated area</p> <p><b>Response</b>            P304+P430 – If inhaled – remove victim to fresh air and keep at rest in a position comfortable for breathing            P312 – Call a POISON CENTER or doctor/physician if you feel unwell</p> <p><b>Storage</b>            P405 – Store locked up</p> <p><b>Disposal</b>            P501 – Dispose of contents/container in accordance with local/provincial/federal regulations</p>

## SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Identity	Concentration (Percent weight/weight)	CAS Number
Bupivacaine Hydrochloride	0.5	73360-54-0
Epinephrine Bitartrate	0.0005	51-42-3

## 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.
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.

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## SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions:	Caution should be used to prevent against ingestion and contact with eyes. Wear safety glasses with side shields.
Environmental precautions:	Prevent spills from entering sewers and watercourses. Cover drains.
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.

## 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 with rubber stopper and cap
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>
	Bupivacaine Hydrochloride	Not available	Not available	Not available	Not available
	Epinephrine Bitartrate	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

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Engineering Controls (e.g. ventilation, enclosed process, specify):	Not normally required
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### 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
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
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:	Acute measures of toxicity (i.e. LD50 and LC50) are not available for this mixture. LD50 for Bupivacaine Hydrochloride: 18 mg/kg oral rat LD50 for Epinephrine Bitartrate: 4 mg/kg oral mouse
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 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:	Animal studies have reported decreased survival rates of pups at levels 5 and 9 times the maximum recommended daily human dose.
Specific Target Organ Toxicity – Single Exposure:	Causes central nervous system effects such as drowsiness, confusion, excitability and nervousness. Acts as a depressant on the cardiovascular system.
Specific Target Organ Toxicity – Repeated Exposure:	May cause hypersensitivity. Associated with the development of methemoglobinemia.
Aspiration Hazard:	Not available. Not expected to be of concern.

### 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**

UN Number:	Not available
UN Proper Shipping Name:	Not available
Transport Hazard Classes:	Not available
Packing Group:	Not available
Environmental Hazards:	Not available
Special Precautions for User:	Avoid temperature extremes. Prevent from freezing.

### **SECTION 15: REGULATORY INFORMATION**

OSHA Regulatory Status:	Epinephrine bitartrate (epinephrine salt) is <u>not</u> listed as a hazardous product in the RCRA (EPA) and CERCLA (EPA) regulations.
Regulatory Status:	This product is exempt from current WHMIS legislation as a drug product

### **SECTION 16: OTHER INFORMATION**

Name of person or group that prepared MSDS:	Septodont in conjunction with a third party consultant
Phone #:	519-623-4800
MSDS Version #:	# 5 (replaces V.4 of July 19, 2013)

*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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