


SAFETY DATA SHEET

PRODUCT ID: BUPIVACAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Bupivacaine Hydrochloride and Epinephrine Injection
Manufacturer:	Novocol Pharmaceutical of Canada, Inc. 25 Wolseley Court Cambridge, ON N1R 6X3 519-623-4800 http://www.septodont.com/
Emergency Phone Number:	ChemTel LLC (800)255-3924 (North America) +1 (813)248-0585 (International)
Product Use:	Local anesthetic solution for use in peripheral nerve blocks
Date of Preparation:	July 12, 2021

SECTION 2: HAZARDS IDENTIFICATION

Classification:	This product is exempt from WHMIS 2015 as a drug product. Information provided is for worker education and training purposes. <u>Equivalent</u> Class: Specific Target Organ Toxicity – Single Exposure: Narcotic effects, Category 3 Acute Toxicity, Category 5
<u>Equivalent</u> GHS Label Symbol:	
Hazard Statements:	Warning 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. CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOPICAL INFORMATION 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:	Prevention P261 – Do not breathe mist/vapours/spray P271 – Use in a well-ventilated area Response

SAFETY DATA SHEET

PRODUCT ID: BUPIVACAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION

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
Storage
P405 – Store locked up
Disposal
P501 – Dispose of contents/container in accordance with local/provincial/federal regulations

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.

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.

SAFETY DATA SHEET

PRODUCT ID: BUPIVACAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION

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 ^a		Ontario	
		TWA ^b	STEL ^c	TWA ^b	STEL ^c
	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):	Impermeable gloves (e.g. nitrile, natural rubber)
Respiratory (specify):	Not normally required
Eye (specify):	Safety glasses with side shields or goggles if a splash hazard exists
Footwear (specify):	Not normally required
Other Equipment (specify):	Wear protective clothing to prevent skin exposure Resuscitative equipment and drugs should be available during dental procedures
Engineering Controls (e.g. ventilation, enclosed process, specify):	Not normally required

SAFETY DATA SHEET

PRODUCT ID: BUPIVACAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION

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

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
-----------------	---

SAFETY DATA SHEET

PRODUCT ID: BUPIVACAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION

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.
-----------	--

SECTION 14: TRANSPORTATION INFORMATION

UN Number:	Not available
UN Proper Shipping Name:	Not available

SAFETY DATA SHEET

PRODUCT ID: BUPIVACAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION

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

SDS Version#:	# 6 (replaces V.5 of July 11, 2016)
---------------	-------------------------------------

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.