

SAFETY DATA SHEET

PRODUCT ID: BUPIVACAINE HYDROCHLORIDE INJECTION

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Bupivacaine Hydrochloride Injection, 0.5%	
Chemical Name:	2-Piperidinecarboxamide, 1-butyl-N-(2,6-dimethylphenyl)-, monohydrochloride, monohydrate	
Item Number:	949-4013; 589-1674	
Manufacturer / Distributor:	Novocol Pharmaceutical of Canada, Inc. 25 Wolseley Court Cambridge, ON N1R 6X3 519-623-4800 http://www.septodont.com/	Henry Schein Inc. 135 Duryea Road Melville, NY 11747 631-843-5500 www.henryschein.com
Emergency Phone Number:	ChemTel LLC (800)255-3924 (North America) +1 (813)248-0585 (International)	
Product Use:	Bupivacaine is indicated for the production of local or regional anesthesia for surgery, dental and oral surgery procedures, diagnostic and therapeutic procedures, and for obstetrical procedures.	
Date of Preparation:	July 12, 2021	

SECTION 2: HAZARDS IDENTIFICATION

GHS Classification:	This product is exempt from WHMIS 2015 as a drug product. Information provided is for worker education and training purposes.
GHS Label Symbol:	None
Applicable GHS Hazard Statements:	Warning H336 - May cause drowsiness or dizziness. H303 - May be harmful if swallowed. 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. CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOPOL 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
Applicable GHS Precautionary Statements:	Prevention P261 – Do not breathe mist/vapours/spray. P271 – Use in a well-ventilated area. P280 – Wear eye protection. Response

SAFETY DATA SHEET

PRODUCT ID: BUPIVACAINE HYDROCHLORIDE INJECTION

P304+P430 – If inhaled – remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312 – Call a POISON CENTER or doctor/physician.
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 (0.5% Solution)	CAS Number
Bupivacaine Hydrochloride Monohydrate	5.0 mg	73360-54-0
Sodium Chloride	8 mg	7647-14-5
Hydrochloric Acid	Up to 0.1 ml (pH adjustment)	7647-01-0
Sodium Hydroxide	Up to 0.1 ml (pH adjustment)	1310-73-2
Water for Injection	Remainder	7732-18-5

SECTION 4: FIRST AID MEASURES

Inhalation:	Remove patient to fresh air. If patient is not breathing, provide artificial respiration. Get medical attention.
Eye Contact:	Immediately 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. Get medical attention if irritation develops or persists.
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).

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.

SAFETY DATA SHEET

PRODUCT ID: BUPIVACAINE HYDROCHLORIDE INJECTION

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:	Avoid use near open flame.
Storage Requirements:	Store at 20 to 25°C (68 to 77°F). Do not refrigerate.
Packaging:	30 mL USP Type 1 glass vial with brombutyl or chlorobutyl rubber stopper and crimped aluminum flip cap
Sensitivity to Mechanical Impact:	Product is not sensitive.
Sensitivity to Static Discharge:	Product is not sensitive.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:	Chemical Agent	Occupational Exposure Limits (OEL)					
		ACGIH ^a		Ontario		Other	
		TWA ^b	STEL ^c	TWA ^b	STEL ^c	TWA ^b	STEL ^c
	Bupivacaine Hydrochloride	Not available	Not available	Not available	Not available	Not available	Not available
	Sodium Hydroxide	Not available	2 mg/m ³ C ^d	Not available	2 mg/m ³ C ^d	Not available	Not available
	Hydrogen Chloride	Not available	2 ppm C ^d	Not available	2 ppm C ^d	Not available	Not available

a – American Conference of Governmental Industrial Hygienists

b – Time Weighted Average

c - Short-term Exposure Limit

d – Ceiling 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

SAFETY DATA SHEET

PRODUCT ID: BUPIVACAINE HYDROCHLORIDE INJECTION

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid
Odour and Appearance:	Clear, colourless and odourless
Odour Threshold:	Not available
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:	Not available
Incompatible Materials:	Incompatible with compounds which react violently with water
Hazardous Decomposition Products:	Not available

SAFETY DATA SHEET

PRODUCT ID: BUPIVACAINE HYDROCHLORIDE INJECTION

SECTION 11: TOXICOLOGICAL INFORMATION

Routes 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 <input checked="" type="checkbox"/> Injection
Acute Toxicity:	Acute measures of toxicity (i.e. LD50 and LC50) are not available for the active ingredient and this mixture. LD50 for Bupivacaine Hydrochloride: 18 mg/kg oral-rabbit LD50 for Sodium Hydroxide: 4090 mg/kg oral-rat
Skin Corrosion/Irritation:	Non-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 (rats and rabbits) at levels 5 and 9 times the maximum recommended daily human dose.
Specific Target Organ Toxicity – Single Exposure:	Not available
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 for Bupivacaine hydrochloride Hydrochloric Acid – Aquatic LC50: 829 mg/L @96 hrs, estimated – fish Sodium Chloride – Aquatic EC50: 340.7 mg/L @48 hrs – water flea
Persistence / Degradability:	Not available
Bioaccumulation / Accumulation:	Not available
Mobility in Environmental Media:	Not available
Other Adverse Effects:	Not available

SAFETY DATA SHEET

PRODUCT ID: BUPIVACAINE HYDROCHLORIDE INJECTION

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
Transport Hazard Classes:	Not available
Packing Group:	Not available
Environmental Hazards:	Not available
Special Precautions for User:	None

SECTION 15: REGULATORY INFORMATION

This product has been classified in accordance with the hazard criteria of the *Hazardous Products Regulations* and the SDS contains all the information required by the *Hazardous Products Regulations*.

Regulatory Status:	This product is exempt from current WHMIS legislation as a drug product.
--------------------	--

SECTION 16: OTHER INFORMATION

SDS Version#:	# 2 (replaces V.1 of May 20, 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.