

Document Detail

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Title: Mepivacaine HCl (3% Polocaine) - MSDS - Novocol
Comment
Status: CURRENT
Effective Date: 08-Mar-2013

Approvals

<u>Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
Pharma Document Control	Ivi R. Shaw	08-Mar-2013 9:35 pm	GMT
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MATERIAL SAFETY DATA SHEET

PRODUCT ID: MEPIVACAINE HYDROCHLORIDE INJECTION

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Mepivacaine Hydrochloride 3% Injection
Brand Name:	3% POLOCAINE® DENTAL (Mepivacaine Hydrochloride 3%, Injection)
Manufacturer / Supplier:	DENTSPLY Pharmaceutical 1301 Smile Way York, PA, USA 1-800-989-8825 http://www.dentsply.com
Prepared By:	Novocol Pharmaceutical in conjunction with a third party consultant
Emergency Phone Number:	1-416-522-3854
Product Use:	Local anesthetic solution for use in peripheral nerve blocks
Date of Preparation:	August 15, 2010

SECTION 2: HAZARDS IDENTIFICATION

Emergency Overview:	<p>Clear, odourless liquid 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. DOES NOT CONTAIN SODIUM BISULFITE</p>
WHMIS Regulatory Status:	Not WHMIS-Controlled
Potential Health Effects:	<p>Routes of Exposure: eye, skin, ingestion Eye: May cause irritation, allergic reaction Skin: May cause irritation, allergic reaction Ingestion: 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 PHARMACOPIAL INFORMATION</p>
Potential Environmental Effects:	Not available

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SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Identity	Concentration (Percent weight/weight)	CAS Number	LD ₅₀	LC ₅₀
Mepivacaine Hydrochloride	3	1722-62-9	310 mg/kg oral mouse	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.
Injection:	Get immediate medical attention.

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 with rubber stopper and cap

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
	Mepivacaine Hydrochloride	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
Melting/Freezing Point (°C):	0°C

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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:	Evidence of human teratogenicity has been identified for this compound. Behavioral abnormalities have been reported in rats injected with mepivacaine.
Mutagenicity:	Not available
Sensitivity to Product:	Not available

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity:	Not available
Persistence / Degradability:	Not available
Bioaccumulation / Accumulation:	Not available
Mobility in Environmental Media:	Not available

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PRODUCT ID: MEPIVACAINE HYDROCHLORIDE INJECTION

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*.

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

SECTION 16: OTHER INFORMATION

Name of person or group that prepared MSDS: Environmental Health & Safety

Phone #: 519-623-4800

MSDS Version#: # 3 (replaces V.2 of March 9, 2007)

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