

MATERIAL SAFETY DATA SHEET

PRODUCT ID: MEPIVACAINE HYDROCHLORIDE WITH LEVONORDEFRIN INJECTION

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Mepivacaine Hydrochloride 2% with Levonordefrin 1:20,000 Injection
Brand Name:	Isocaine 2% (Mepivacaine Hydrochloride 2% with Levonordefrin 1:20,000 Injection) Scandonest 2% L (Mepivacaine Hydrochloride 2% with Levonordefrin 1:20,000 Injection)
Manufacturer / Supplier:	Novocol Pharmaceutical of Canada, Inc. P. O. Box 68 Cambridge, Ontario, Canada N1R 5S9 519-623-4800 http://www.septodont.ca/
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 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.
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: 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

MATERIAL SAFETY DATA SHEET

PRODUCT ID: MEPIVACAINE HYDROCHLORIDE WITH LEVONORDEFRIN INJECTION

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Identity	Concentration (Percent weight/weight)	CAS Number	LD ₅₀	LC ₅₀
Mepivacaine Hydrochloride	2	1722-62-9	310 mg/kg oral mouse	Not available
Levonordefrin	0.005	829-74-3	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.
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.

MATERIAL SAFETY DATA SHEET

PRODUCT ID: MEPIVACAINE HYDROCHLORIDE WITH LEVONORDEFRIN INJECTION

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
	Levonordefrin	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

MATERIAL SAFETY DATA SHEET

PRODUCT ID: MEPIVACAINE HYDROCHLORIDE WITH LEVONORDEFRIN INJECTION

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

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

MATERIAL SAFETY DATA SHEET

PRODUCT ID: MEPIVACAINE HYDROCHLORIDE WITH LEVONORDEFRIN INJECTION

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

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:	Levonordefrin 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.

Novocol Pharmaceutical of Canada, Inc. believes the information to be reliable but expressly disclaims any liability for providing such information and toxicology to our customers.