

SAFETY DATA SHEETS

This SDS packet was issued with item:

071200559

N/A


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:	July 19, 2013

SECTION 2: HAZARDS IDENTIFICATION

Classification:	Narcotic effects, Category 3
GHS Label Symbol:	
Hazard Statements:	<p>Warning</p> <p>H336 - May cause drowsiness or dizziness</p> <p>May cause skin and/or eye irritation</p> <p>Causes central nervous system effects such as drowsiness, confusion, excitability and nervousness. Acts as a depressant on the cardiovascular system.</p> <p>Avoid use in individuals with hypersensitivities to amide-type anesthetics. Use with caution in individuals with diabetes and/or severe hypertension.</p> <p>CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOLOGICAL INFORMATION</p> <p>Signs and Symptoms of Overexposure: Drowsiness, confusion, excitability, nervousness, drop in blood pressure, fatigue, bluish discoloration of fingernails, lips, or skin, difficulties in breathing.</p> <p>DOES NOT CONTAIN SODIUM BISULFITE</p>
Precautionary Statements:	<p>Prevention</p> <p>P261 – Do not breathe mist/vapours/spray</p> <p>P271 – Use in a well-ventilated area</p> <p>Response</p> <p>P304+P430 – If inhaled – remove victim to fresh air and keep at rest in a position comfortable for breathing</p> <p>P312 – Call a POISON CENTER or doctor/physician if you feel unwell</p> <p>Storage</p>

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	P405 – Store locked up Disposal P501 – Dispose of contents/container in accordance with local/provincial/federal regulations
WHMIS Regulatory Status:	Not WHMIS-Controlled

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Identity	Concentration (Percent weight/weight)	CAS Number
Mepivacaine Hydrochloride	3	1722-62-9

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.
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.
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

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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
	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

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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

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 checked="" type="checkbox"/> Skin Absorption <input checked="" type="checkbox"/> Eye Contact <input checked="" type="checkbox"/> Inhalation <input checked="" type="checkbox"/> Ingestion
Acute Toxicity:	Not expected to be acutely toxic. Acute measures of toxicity (i.e. LD50 and LC50) are not available for this mixture. LD50 for Mepivacaine Hydrochloride: 310 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

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	Occupational Safety and Health Administration (OSHA).
Reproductive Toxicity:	Evidence of human teratogenicity has been identified for this compound. Behavioral abnormalities have been reported in rats injected with mepivacaine.
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
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

Basic Shipping Description:	Not available
Additional Information:	Not available
Special Precautions:	Avoid temperature extremes. Prevent from freezing.
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.

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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:	Not available
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Regulatory Status:	This product is exempt from WHMIS as a drug product
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SECTION 16: OTHER INFORMATION

Name of person or group that prepared MSDS:	Novocol Pharmaceutical in conjunction with a third party consultant
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Phone #:	519-623-4800
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MSDS Version#:	# 4 (replaces V.3 of August 15, 2010)
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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.



MATERIAL SAFETY DATA SHEET
3% Polocaine™ Dental (Mepivacaine Hydrochloride 3%, injection)

MSDS-017-POLOCAINE- US REV.00, November 2014

DENTSPLY International
DENTSPLY Pharmaceutical

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC)
1907/2006, Regulation (EC) 1272/2008 and Regulation
(EC) 453/2010)

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled): 3% Polocaine™ Dental (Mepivacaine Hydrochloride 3%, injection)
Part/Item Number(s): 34416

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use: Local anesthetic solution for use in peripheral nerve blocks
Restrictions on Use: For Professional Use Only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: DENTSPLY Pharmaceutical
Manufacturer/Supplier Address: 1301 Smile Way
York, PA 17404
Manufacturer/Supplier Telephone Number: 1-800-989-8825
Email address: webmaster@dentsply.com

1.4 Emergency Telephone Number:

Please report all incidents to the company contacts listed above.

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:		
Health	Environmental	Physical
Not Hazardous	Not Hazardous	Not Hazardous

EU Classification: Xn R22

2.2 Label Elements:

3% Polocaine™ Dental

No.: MSDS-017-POLOCAINE US

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None Required

Signal Word: None

Hazard Phrases	Precautionary Phrases
None Required	None Required

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Non-hazardous ingredients	Mixture	Mixture	Not Hazardous	96
Mepivacaine Hydrochloride	1722-62-9	217-244-0	T R25 Acute Tox. 3 H301	3

Refer to Section 16 for the full text of the GHS and EU Classifications.

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:

Eye	Flush victim's eyes with large quantities of water, while holding the eyelids apart. Get medical attention if irritation develops or persists.
Skin	Wash skin thoroughly with soap and water. Get medical attention if irritation occurs and persists. Remove and launder clothing before re-use.
Inhalation	Remove victim to fresh air. Get medical attention if symptoms of exposure occur.
Ingestion	If small quantities are swallowed, rinse out mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious or drowsy person. Get medical attention if you feel unwell.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

May cause slight eye and skin irritation. Skin contact may cause numbness.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

Immediate medical attention should not be required.

Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

5. FIRE-FIGHTING MEASURES







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5.1 Extinguishing Media:	Use material appropriate for surrounding materials.
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5.2 Special Hazards Arising from the Substance or Mixture:
Product is not flammable. Thermal decomposition may yield chlorine or oxides of nitrogen.

5.3 Advice for Fire-Fighters:			
Fire Fighting Procedures:	Fight fire from safe distance or protected location. Water may be ineffective unless used as a fine spray or fog. Use water to cool fire-exposed containers. Contain water used in firefighting from entering sewers or natural waterways.		
Precautions for Fire Fighters:	Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection.		
Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:			
Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing as described in Section 8.			
Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	HANDS	RESPIRATORY	SKIN
			

6.2 Environmental Precautions:
Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:
Contain and collect using an inert absorbent material and place in appropriate containers for disposal. Clean spill site with water.

6.4 Reference to Other Sections:



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Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling:

Avoid contact with skin, eyes or clothing. Wear protective clothing and equipment as described in Section 8. Avoid breathing mists or vapors. Wash thoroughly with soap and water after handling.

7.2 Conditions for Safe Storage, Including Any Incompatibilities: Store in accordance with label recommendations.

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Non-hazardous Ingredients	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Mepivacaine Hydrochloride	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with local exhaust ventilation to minimize exposure levels.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Follow facility requirements. Wear safety glasses when the possibility exists for eye contact due to splashing or spraying material.

Specific Skin Protection: Follow facility requirements. Wear impervious gloves to prevent skin contact.

Specific Respiratory Protection: Follow facility requirements.

Specific Thermal Hazards: None required.



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Recommended Personal Protective Equipment			
EYES/FACE	HANDS	RESPIRATORY	SKIN

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Clear liquid	Explosive limits:	LEL: Not available UEL: Not available
Odor:	Odorless	Vapor pressure (mmHg):	Same as water
Odor threshold:	Not available	Vapor density:	Same as water
pH:	Not available	Relative density:	1.0
Melting/freezing point:	32°F (0°C)	Solubility(ies):	Complete
Initial boiling point and boiling range:	212°F (100°C)	Partition coefficient: n-octanol/water:	Not available
Flash point:	Not flammable	Auto-ignition temperature:	Not available
Evaporation rate:	Same as water	Decomposition temperature:	Not available
Flammability (solid, gas):	Not applicable	Viscosity:	Not available
Explosive Properties:	None	Oxidizing Properties:	None

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Not reactive.

10.2 Chemical Stability: Stable.



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10.3 Possibility of Hazardous Reactions: None known.

10.4 Conditions to Avoid: None known.

10.5 Incompatible materials: Avoid contact with water-reactive materials.

10.6 Hazardous Decomposition Products: Chlorine and oxides of nitrogen.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Liquid can cause slight irritation with tears and blurred vision. May cause numbness of sensation.

Skin: May cause slight skin irritation and numbness.

Ingestion: May cause slight gastrointestinal irritation.

Inhalation: May cause slight respiratory tract irritation with coughing and anesthetic effects.

Chronic Health Effects: None known.

Irritation: May cause slight eye and skin irritation.

Corrosivity: No data available.

Sensitisation: Product is not expected to cause sensitization.

Carcinogenicity: None of the components are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

Mutagenicity: No data available.

Medical Conditions Aggravated by Exposure: None known.

Acute Toxicity Data:

Mepivacaine hydrochloride: Oral mouse LD50 310 mg/kg

ATE_{mix} 16,667 mg/kg

Reproductive Toxicity Data: Evidence of human teratogenicity has been identified for this compound. Behavioral abnormalities have been reported in rats injected with mepivacaine.

Specific Target Organ Toxicity (STOT):

Single Exposure: None known.

Repeated Exposure: Repeat or chronic exposure may cause hypersensitivity and the development of methemoglobinemia.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:



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No data available.

12.2 Persistence and Degradability: No data available.

12.3 Bio-accumulative Potential: No data available.

12.4 Mobility in Soil: No data available.

12.5 Results of PBT and vPvB Assessment: No data available.

12.6 Other Adverse Effects: No adverse effects are expected

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with all national and local regulations.

Properties (Physical/Chemical) Affecting Disposal: This product will polymerize when exposed to sunlight. Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers.

Waste Treatment Recommendations: Dispose in accordance with national and local regulations.

14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	None	Not Regulated	None	None	Not applicable
ADR/RID	None	Not Regulated	None	None	Not applicable
IMDG	None	Not Regulated	None	None	Not applicable
IATA/CAO	None	Not Regulated	None	None	Not applicable

14.6 Special Precautions for User: Not applicable.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product is not subject to reporting under CERCLA. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.



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Toxic Substances Control Act (TSCA): This product is a medical device and not subject to chemical notification requirements.

Clean Water Act (CWA): This material is not regulated under the Clean Water Act.

Clean Air Act (CAA): This material is not regulated under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard:	No	Pressure Hazard:	No
Delayed Hazard:	No	Reactivity Hazard:	No
Fire Hazard:	No		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
None		

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

Components	C.A.S. #	WT %
None		

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

Canadian Environmental Protection Act: This product is a pharmaceutical formulation and not subject to chemical notification requirements.

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

European Inventory of Existing Chemicals (EINECS): This product is a pharmaceutical formulation and not subject to chemical notification requirements.

EU REACH: This product is a pharmaceutical formulation and not subject to chemical notification requirements.

Australian Inventory of Chemical Substances: This product is a pharmaceutical formulation and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a pharmaceutical formulation and not subject to chemical notification requirements.



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Japanese Existing and New Chemical Substances: This product is a pharmaceutical formulation and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a pharmaceutical formulation and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a pharmaceutical formulation and not subject to chemical notification requirements.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 1 Flammability – 0 Physical Hazard– 0

Full text of Classification abbreviations used in Section 2 and 3:

Xn Harmful

T Toxic

R22 Harmful if swallowed.

R25 Toxic if swallowed.

Acute Tox. 3 Acute Toxicity Category 3

H301 Toxic if swallowed.

Supersedes: 19 July 2013

Date of Current Revision: 3 November 2014

Revision Summary: Converted MSDS to Reach SDS. Updated all sections.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.