

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

076313068

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078915926

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

075452669 075452693 075452727 076313001 076313019 076313050

# MATERIAL SAFETY DATA SHEET

**PRODUCT ID: LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION**

## SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Lidocaine hydrochloride 2% and Epinephrine 1:50,000 Injection Lidocaine hydrochloride 2% and Epinephrine 1:100,000 Injection
Brand Name:	<b>OCTOCAINE® 50</b> (Lidocaine Hydrochloride 2% and Epinephrine 1:50,000 Injection) * <b>LIGNOSPAN® FORTE</b> (Lidocaine Hydrochloride 2% and Epinephrine 1:50,000 Injection) <b>OCTOCAINE® 100</b> (Lidocaine Hydrochloride 2% and Epinephrine 1:100,000 Injection) <b>LIGNOSPAN® STANDARD</b> (Lidocaine Hydrochloride 2% and Epinephrine 1:100,000 Injection)
Manufacturer / Supplier:	Novocol Pharmaceutical of Canada, Inc. P. O. Box 68 Cambridge, Ontario, Canada N1R 5S9 519-623-4800 <a href="http://www.septodont.ca/">http://www.septodont.ca/</a>
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. Use with caution in individuals with diabetes and/or severe hypertension.
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: Not available 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. <b>CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOLOGICAL INFORMATION</b>
Potential Environmental Effects:	Not available

# MATERIAL SAFETY DATA SHEET

**PRODUCT ID: LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION**

## **SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS**

Chemical Identity	Concentration (Percent weight/weight)	CAS Number	LD <sub>50</sub>	LC <sub>50</sub>
Lidocaine Hydrochloride	2	137-58-6	292 mg/kg oral mouse	Not available
Epinephrine	0.001 - 0.002	51-43-4	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.

## **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: LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE 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 cartridges with rubber stopper and cap

## SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:	Chemical Agent	Occupational Exposure Limits (OEL)			
		ACGIH <sup>a</sup>		Ontario	
		TWA <sup>b</sup>	STEL <sup>c</sup>	TWA <sup>b</sup>	STEL <sup>c</sup>
	Lidocaine Hydrochloride	Not available	Not available	Not available	Not available
	Epinephrine	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

# MATERIAL SAFETY DATA SHEET

**PRODUCT ID: LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION**

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:	No significant effects were observed on fetal development. However, animal studies have found that continuous exposure throughout pregnancy may decrease birth weight.
Mutagenicity:	Not available
Sensitivity to Product:	Not available

## SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity:	Not available
Persistence / Degradability:	Not available
Bioaccumulation / Accumulation:	Not available

# MATERIAL SAFETY DATA SHEET

**PRODUCT ID: LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION**

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: Epinephrine 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.*


# SAFETY DATA SHEET

**PRODUCT ID: LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION**

## SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Lidocaine hydrochloride 2% and Epinephrine 1:50,000 Injection Lidocaine hydrochloride 2% and Epinephrine 1:100,000 Injection
Brand Name:	<b>OCTOCAINE® 50</b> (Lidocaine Hydrochloride 2% and Epinephrine 1:50,000 Injection) <b>LIGNOSPAN® FORTE</b> (Lidocaine Hydrochloride 2% and Epinephrine 1:50,000 Injection) <b>OCTOCAINE® 100</b> (Lidocaine Hydrochloride 2% and Epinephrine 1:100,000 Injection) <b>LIGNOSPAN® STANDARD</b> (Lidocaine Hydrochloride 2% and Epinephrine 1:100,000 Injection)
Manufacturer / Supplier:	Septodont 25 Wolseley Court Cambridge, Ontario, Canada N1R 6X3 519-623-4800 <a href="http://www.septodont.com/">http://www.septodont.com/</a>
Prepared By:	Septodont in conjunction with a third party consultant
Emergency Phone Number:	(519) 623-4800 (Monday-Friday 08:30 to 16:30 EST)
Product Use:	Local anesthetic solution for use in peripheral nerve blocks
Date of Preparation:	July 11, 2016

## SECTION 2: HAZARDS IDENTIFICATION

Classification:	<b>This product is exempt from WHMIS 2015 as a drug product. Information provided is for worker education and training purposes.</b> <u>Equivalent Class:</u> Specific Target Organ Toxicity – Single Exposure: Narcotic effects, Category 3
<u>Equivalent GHS Label Symbol:</u>	
Hazard Statements:	<b>Warning</b> H336 - May cause drowsiness or dizziness 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.

# SAFETY DATA SHEET

## PRODUCT ID: LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION

	<p>CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOPOLIAL 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>
Precautionary Statements:	<p><b>Prevention</b>  P261 – Do not breathe mist/vapours/spray  P271 – Use in a well-ventilated area</p> <p><b>Response</b>  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</p> <p><b>Storage</b>  P405 – Store locked up</p> <p><b>Disposal</b>  P501 – Dispose of contents/container in accordance with local/provincial/federal regulations</p>

## SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Identity	Concentration (Percent weight/weight)	CAS Number
Lidocaine Hydrochloride	2	137-58-6
Epinephrine Bitartrate	0.001 - 0.002	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



# SAFETY DATA SHEET

**PRODUCT ID: LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION**

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 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 <sup>a</sup>		Ontario	
		TWA <sup>b</sup>	STEL <sup>c</sup>	TWA <sup>b</sup>	STEL <sup>c</sup>
	Lidocaine 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):

Not normally required

Respiratory (specify):

Not normally required

Eye (specify):

Not normally required

## SAFETY DATA SHEET

### PRODUCT ID: LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION

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
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

## SAFETY DATA SHEET

**PRODUCT ID: LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION**

### 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 Lidocaine Hydrochloride: 317 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:	No significant effects were observed on fetal development. However, animal studies have found that continuous exposure throughout pregnancy may decrease birth weight.
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.
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# SAFETY DATA SHEET

**PRODUCT ID: LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION**

## 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:	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

Name of person or group that prepared SDS:	Septodont in conjunction with a third party consultant
Phone #:	519-623-4800
SDS Version#:	# 5 (replaces V.4 of July 19, 2013)

*Information and statements contained in this document have been obtained from manufacturers, suppliers and recognized reference sources as provided to or obtained by Septodont.*

*Septodont believes the information to be reliable but expressly disclaims any liability for providing such information and toxicology to our customers.*