This SDS packet was issued with item: 076313068

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 078877706 078915926

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: | OCTOCAINE® 50 (Lidocaine Hydrochloride 2% and Epinephrine 1:50, 000 Injection) LIGNOSPAN® FORTE (Lidocaine Hydrochloride 2% and Epinephrine 1:50, 000 Injection) OCTOCAINE® 100 (Lidocaine Hydrochloride 2% and Epinephrine 1:100, 000 Injection) LIGNOSPAN® STANDARD (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 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. 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. CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOPIAL INFORMATION |
| Potential Environmental Effects: | Not available |

PRODUCT ID: LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION

CAS Number LD50 LC₅₀ **Chemical Identity** Concentration (Percent weight/weight) 292 mg/kg oral 2 137-58-6 Lidocaine Hydrochloride Not available mouse 0.001 - 0.002 51-43-4 Epinephrine 5 mg/kg dermal rat Not available

COMPOSITION / INFORMATION ON INGREDIENTS

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:

SECTION 3:

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. |

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 | | Ontario | |
| | | TWA ^b | STEL° | Τ₩Α ^Ҍ | STEL° |
| | Lidocaine Hydrochloride | Not available | Not available | Not available | Not available |
| | Epinephrine | Not available | Not available | Not available | Not available |
| a – American Conference of Governmental Industr b – Time Weighted Average c - Short-term Exposure Limit | ial Hygienists | | <u>.</u> | | |
| 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 |

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: | Skin Contact Skin Absorption Eye Contact Inhalation 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 |

PRODUCT ID: LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION

| Mobility in Environmental Media: | Not available |
|----------------------------------|---------------|
| Other Adverse Effects: | Not available |

SECTION 13:

DISPOSAL CONSIDERATIONS

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.

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: | OCTOCAINE[®] 50 (Lidocaine Hydrochloride 2% and Epinephrine 7 000 Injection) LIGNOSPAN[®] FORTE (Lidocaine Hydrochloride 2% and Epineph 1:50, 000 Injection) OCTOCAINE[®] 100 (Lidocaine Hydrochloride 2% and Epinephrine 1:100, 000 Injection) LIGNOSPAN[®] STANDARD (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 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. 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. CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOPIAL INFORMATION |
| Potential Environmental Effects: | Not available |

PRODUCT ID: LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION

| Chemical Identity | Concentration (Percent weight/weight) | CAS Number | LD ₅₀ | LC ₅₀ |
|-------------------------|---|------------|-------------------------|------------------|
| 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 |

COMPOSITION / INFORMATION ON INGREDIENTS

| 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: |
|---------|----|
|---------|----|

SECTION 3:

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. |

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: | | Occupational Exposure Limits (OEL) | | | |
|---|---|------------------------------------|---------------|------------------|---------------|
| | Chemical Agent | ACGIH | | Ontario | |
| | | TWA ^b | STEL° | Τ₩Α ^Ϸ | STEL° |
| | Lidocaine Hydrochloride | Not available | Not available | Not available | Not available |
| | Epinephrine | Not available | Not available | Not available | Not available |
| a – American Conference of Governmental Industr b – Time Weighted Average c - Short-term Exposure Limit | ai Hygienists | | | | |
| 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 |

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 |

| RECTION 44 | TOXICOLO |
|-------------|----------|
| SECTION 11: | TUXICULU |

TOXICOLOGICAL INFORMATION

| Route of Entry: | Skin Contact 🗌 Skin Absorption 🛛 Eye Contact 🗌 Inhalation 🖂 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 |

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 <i>Controlled Products Regulations</i> and the MSDS contains all the information required by the <i>Controlled Products Regulations</i> . | |
|--|--|
| 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) |

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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: | OCTOCAINE® 50 (Lidocaine Hydrochloride 2% and Epinephrine 1:50, 000 Injection) |
| | LIGNOSPAN[®] FORTE (Lidocaine Hydrochloride 2% and Epinephrine 1:50, 000 Injection) |
| | OCTOCAINE® 100 (Lidocaine Hydrochloride 2% and Epinephrine 1:100, 000 Injection) |
| | LIGNOSPAN [®] STANDARD (Lidocaine Hydrochloride 2% and Epinephrine 1:100, 000 Injection) |
| Manufacturer / Supplier: | Septodont 25 Wolseley Court Cambridge, Ontario, Canada N1R 6X3 519-623-4800 http://www.septodont.com/ |
| 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: | This product is exempt from WHMIS 2015 as a drug product.Information provided is for worker education and training purposes.Equivalent Narcotic effects, Category 3 |
|------------------------------|---|
| Equivalent GHS Label Symbol: | |
| Hazard Statements: | Warning 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. |

PRODUCT ID: LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION

| | CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOPIAL 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. |
|---------------------------|---|
| Precautionary Statements: | PreventionP261 – Do not breathe mist/vapours/sprayP271 – Use in a well-ventilated areaResponseP304+P430 – If inhaled – remove victim to fresh air and keep at rest in a position comfortable for breathingP312 – Call a POISON CENTER or doctor/physician if you feel unwellStorageP405 – Store locked upDisposalP501 – Dispose of contents/container in accordance with local/provincial/federal regulations |

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:

Г

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 |

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 | | Ontario | |
| | | TWA ^b | STEL ^c | TWA ^b | STEL ^c |
| | 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 Industria b – Time Weighted Average c - Short-term Exposure Limit | al Hygienists | | | | |
| Personal Protective Equipment (PPE): | | | | | |
| Gloves (specify): | Not normally required | | | | |
| Respiratory (specify): | Not normally required | | | | |
| Eye (specify): | Not normally required | | | | |

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 |

PRODUCT ID: LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION

SECTION 11:

TOXICOLOGICAL INFORMATION

| Route of Entry: | \boxtimes Skin Contact \boxtimes Skin Absorption \boxtimes Eye Contact \boxtimes Inhalation \boxtimes 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.

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.