

# SAFETY DATA SHEET

**PRODUCT ID: MEPIVACAINE HYDROCHLORIDE INJECTION**

## SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

|                         |   |
|-------------------------|---|
| Product Name:           | Mepivacaine Hydrochloride 3% Injection  |
| Manufacturer:           | Novocol Pharmaceutical of Canada, Inc.<br>25 Wolseley Court<br>Cambridge, ON N1R 6X3<br>519-623-4800<br><a href="http://www.septodont.com/">http://www.septodont.com/</a> |
| Emergency Phone Number: | ChemTel LLC<br>(800)255-3924 (North America)<br>+1 (813)248-0585 (International)  |
| Product Use:            | Local anesthetic solution for use in peripheral nerve blocks  |
| Date of Preparation:    | July 14, 2021   |

## 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><br><u>Equivalent</u> Class: Specific Target Organ Toxicity – Single Exposure: Narcotic effects, Category 3  |
| <u>Equivalent</u> GHS Label Symbol: |   |
| Hazard Statements:                  | <b>Warning</b><br>H336 - May cause drowsiness or dizziness<br>May cause skin and/or eye irritation<br>Causes central nervous system effects such as drowsiness, confusion, excitability and nervousness. Acts as a depressant on the cardiovascular system.<br>Avoid use in individuals with hypersensitivities to amide-type anesthetics. Use with caution in individuals with diabetes and/or severe hypertension.<br><b>CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOPOLIAL INFORMATION</b><br>Signs and Symptoms of Overexposure: Drowsiness, confusion, excitability, nervousness, drop in blood pressure, fatigue, bluish discoloration of fingernails, lips, or skin, difficulties in breathing.<br><b>DOES NOT CONTAIN SODIUM BISULFITE</b> |
| Precautionary Statements:           | <b>Prevention</b><br>P261 – Do not breathe mist/vapours/spray<br>P271 – Use in a well-ventilated area<br><b>Response</b>   |

# SAFETY DATA SHEET

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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  
**Storage**  
P405 – Store locked up  
**Disposal**  
P501 – Dispose of contents/container in accordance with local/provincial/federal regulations

## SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

| Chemical Identity         | Concentration<br>(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.   |

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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.<br>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> |
|   | Mepivacaine Hydrochloride   | Not available                      | Not available     | Not available    | Not available     |
| a – American Conference of Governmental Industrial Hygienists<br>b – Time Weighted Average<br>c - Short-term Exposure Limit |   |                                    |                   |                  |                   |
| Personal Protective Equipment (PPE):  |   |                                    |                   |                  |                   |
| Gloves (specify):   | Impermeable gloves (e.g. nitrile, natural rubber)   |                                    |                   |                  |                   |
| Respiratory (specify):  | Not normally required   |                                    |                   |                  |                   |
| Eye (specify):  | Safety glasses with side shields or goggles if a splash hazard exists   |                                    |                   |                  |                   |
| Footwear (specify):   | Not normally required   |                                    |                   |                  |                   |
| Other Equipment (specify):  | Wear protective clothing to prevent skin exposure<br>Resuscitative equipment and drugs should be available during dental procedures |                                    |                   |                  |                   |
| Engineering Controls (e.g. ventilation, enclosed process, specify):   | Not normally required   |                                    |                   |                  |                   |

# SAFETY DATA SHEET

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## 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

|                                   |  |
|-----------------------------------|--|
| 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.<br>Acute measures of toxicity (i.e. LD50 and LC50) are not available for this mixture.<br>LD50 for Mepivacaine Hydrochloride: 310 mg/kg oral mouse  |
| Skin Corrosion/Irritation: | May be irritating to the skin.  |

## SAFETY DATA SHEET

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|---|---|
| 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:                              | 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:   | 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. |
|-----------|--|

### 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 |

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Special Precautions for User:

Avoid temperature extremes. Prevent from freezing.

## SECTION 15:

## REGULATORY INFORMATION

OSHA Regulatory Status:

Not available

Regulatory Status:

This product is exempt from current WHMIS legislation as a drug product

## SECTION 16:

## OTHER INFORMATION

SDS Version#:

# 6 (replaces V.5 of July 11, 2016)

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*