



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

SDS-003-POLOCAINE- US REV.00, March 2017

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: 1-416-522-3854

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:



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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. |
| Personal Protective Equipment for First Aid Responders | Wear impermeable gloves to avoid skin contact (e.g. nitrile, natural rubber). |

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.



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

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media: Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.





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.



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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:

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 a cool, dry place. Avoid extremes in temperature.

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



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| |
|---|
| 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. |

| 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): | 17 mm Hg @ 20°C |
| Odor threshold: | Not applicable | Vapor density: | 0.6 (Air=1) |
| 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: | 1 (Butyl Acetate=1) | Decomposition temperature: | Not available |
| Flammability (solid, gas): | Not applicable | Viscosity: | Not available |



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| | | | |
|------------------------------|------|------------------------------|------|
| 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.

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.

Sensitization: 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



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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: Causes central nervous system effects such as drowsiness, confusion, excitability and nervousness. Acts as a depressant on the cardiovascular system

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

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

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: Not available.

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/ICAO | None | Not Regulated | None | None | Not applicable |



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14.6 Special Precautions for User: Avoid temperature extremes. Prevent from freezing.

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.

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.



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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.

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: November 2014

Date of Current Revision: 15 March 2017

Revision Summary: Converted MSDS to Reach SDS. Changed MSDS-017 to SDS-003, for new format

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