

MATERIAL SAFETY DATA SHEET: ODONTOCAINE® 2% WITH EPINEPHRINE ANESTHETIC PRANFS-023

1 IDENTIFICATION

1.1 Chemical name:

1.1.1 Mepivacaine: N-(2,6-dimethylphenyl)-1-methyl-piperidine-2 carboxamide.

Epinephrine: (R)-4-[1-hydroxy-2-(methylamino)ethyl] benzene-1,2-diol

1.2 Generic name: Mepivacaine with Epinephrine

1.3 Synonym: Epinephrine is known as adrenaline.

1.4 CAS Number:

1.4.1 Mepivacaine: 96-88-8

1.4.2 Epinephrine: 51-43-4

2 COMPOSITION INFORMATION

2.1 Hazardous components: Mepivacaine, Epinephrine

2.2 Non Hazardous components: N.A.

3 IDENTIFICATION OF DANGERS

3.1 Characteristics of the material translucent liquid free of particulate matter.

3.2 Appearance in case of emergency: Pink solution with particulate matter.

3.3 Potential adverse health effects: Toxic in high concentrations.

4 FIRST AID MEASURES

4.1 First aid and emergency procedures in case of:

- Inhalation: No evidence of intoxication.
- Contact with eyes: Flush eyes with plenty of water for at least 15 minutes. Get medical attention, if irritation persists.
- Contact with the skin: There is no evidence of negative toxic implications when in contact with the skin
- Ingestion: Get immediate medical attention. Do not induce vomiting unless instructed to do so by poison control or physician.

Created		Elaborated by:	Reviewed by:	
2011-10-05		Pharmaceutical Analyst	Quality Assurance Coordinator	
Class	Pages	Approved by:	Updated	Version
E	1 de 5	Anesthetics Technical Director	2019-05-31	3

MATERIAL SAFETY DATA SHEET: ODONTOCAINE® 2% WITH EPINEPHRINE ANESTHETIC PRANFS-023

- 4.2 Antidote: Does not apply.
4.3 Information for doctors: Does not apply.

5 ACTION IN CASE OF FIRE

- 5.1 Flammable Properties: Not flammable
5.2 Means of extinguishing: Fire may be extinguished with fire extinguishers type CO₂, ABC, BC, Solkaflan.
5.3 Instructions for firefighting: Use full respiratory equipment and protective clothes

6 ACTION IN CASE OF ACCIDENTAL SPILL

- 6.1 Techniques, procedures and materials in case of:
– Small spills: Put on gloves, prevent any spills down drains or canals and pick up with absorbent cloths.
– Large Spills: prevent any spills down drains or canals, pick up in airtight plastic containers.
6.2 Other considerations: The residues of the local anesthetic, Odontocaine® 2% with Epinephrine must be disposed of by incineration in treatment plants or according to the acting regulations of each country.

7 HANDLING AND STORAGE OF THE PRODUCT

- 7.1 Handling: The indicated for a pharmaceutical product, according to the acting regulations of each country
7.2 Storage: Must be stored in a dry, fresh, place, protected from direct light and heat or intense lighting. It should be stored at a temperature below 30.0 °C (111.6°F).
Keep out of the reach of children
7.3 The injectable product Odontocaine® 2% with Epinephrine must be transported protected from direct light and heat and intense lighting. It should be stored at a temperature below 30.0 °C (111.6°F).

Created		Elaborated by:	Reviewed by:	
2011-10-05		Pharmaceutical Analyst	Quality Assurance Coordinator	
Class	Pages	Approved by:	Updated	Version
E	2 de 5	Anesthetics Technical Director	2019-05-31	3

MATERIAL SAFETY DATA SHEET: ODONTOCAINE® 2% WITH EPINEPHRINE ANESTHETIC PRANFS-023

8 EXPOSURE CONTROLS AND PERSONAL PROTECTION

- 8.1 Conditions for control of exposure: Use adequate gloves. The most adequate gloves depend on a series of factors such as physical resistance, sensibility level, and level of impermeability of the material of the glove. For this case surgical latex gloves provide a proper protection. The gloves must be replaced regularly being careful not to tear them.
- 8.2 Personal protection equipment: Does not apply.
- Respiratory Equipment: Does not apply.
 - Eye Protection: Goggles.
- 8.3 Exposure Parameters: None reported.

9 PHYSICAL AND CHEMICAL PROPERTIES OF THE PRODUCT

- Appearance or shape: Translucent liquid free of particulate matter
- Odor: odorless
- Physical State: Liquid
- pH: 3.5 – 5.0
- Vapor Pressure: Does not apply
- Vapor Density: Does not apply
- Boiling Point: None determined
- Freezing or Fusion Point (Specify which): Does not apply
- Solubility in water: Solvable
- Specific Gravity or Density: 1.0 approximately.
- Size of particle: Does not apply
- Content of Volatile Organic Components: Does not apply
- Softening Point: Does not apply
- Speed of evaporation: Does not apply
- Viscosity: Does not apply
- Gross Density (bulk density): Does not apply
- Volatility Percentage: Does not apply
- Partition coefficient octanol/water: None Determined
- Concentration of saturated vapor: Does not apply

10 STABILITY AND REACTIVITY

- 10.1 Chemical stability: Strong oxidizing substances must be avoided.
- 10.2 Conditions to avoid: This product decomposes at temperatures of 35 °C (120.6 °F).

Created		Elaborated by:	Reviewed by:	
2011-10-05		Pharmaceutical Analyst	Quality Assurance Coordinator	
Class	Pages	Approved by:	Updated	Version
E	3 de 5	Anesthetics Technical Director	2019-05-31	3

MATERIAL SAFETY DATA SHEET: ODONTOCAINE® 2% WITH EPINEPHRINE ANESTHETIC PRANFS-023

- 10.3 Incompatibility with other materials: Incompatible with compounds which react violently with water.
- 10.4 Dangerous decompositions products: None reported.
- 10.5 Dangerous polymerization: Does not apply.

11 TOXICOLOGICAL INFORMATION

- 11.1 Acute toxicity: In excessive doses, high concentration of plasma, depression of the cardiovascular system (hypotension, irregular or slow heart rate, paleness, increased sweating) may occur. It may lead to heart arrest, toxicity of the central nervous system (double or blurred vision, confusion, dizziness, excitation, nervousness and anxiety).
In patients with acidosis or hypoxia, the risk of severe allergic reactions is greater. These reactions involve the central nervousness and cardiovascular systems. The local anesthetics must be administered carefully in patients with anemia, severe heart diseases or insufficient circulation of any sort. Local anesthetics must be avoided when there is inflammation in the area where the injection was applied.
- 11.2 Chronic Toxicity: None Reported.
- 11.3 Other Information: Does not apply.

12 ECOLOGICAL INFORMATION

The residues of the local anesthetic Odontocaine® 2% with Epinephrine must be destroyed by incineration in treatment plants or according to the acting regulations of each country.

13 DISPOSAL CONSIDERATIONS

The residues of the anesthetic Odontocaine® 2% with Epinephrine must be disposed of according to the acting local regulations
WARNING: The local laws regulations and restrictions may change or be subject to different interpretations and differ from national laws, due to this the disposal of the materials and their packaging may vary from those in this document.

Created		Elaborated by:	Reviewed by:	
2011-10-05		Pharmaceutical Analyst	Quality Assurance Coordinator	
Class	Pages	Approved by:	Updated	Version
E	4 de 5	Anesthetics Technical Director	2019-05-31	3

MATERIAL SAFETY DATA SHEET: ODONTOCAINE® 2% WITH EPINEPHRINE ANESTHETIC PRANFS-023

14 TRANSPORT INFORMATION

- 14.1 Dangerous Materials: None
- 14.2 Type of Risk: Non Hazardous Material
- 14.3 UN: Number: None available
- 14.4 IATA Classification: Non Hazardous Material.
- 14.1 The injectable product Odontocaine® 2% with Epinephrine must be transported protected by direct light, heat and strong lighting. It should be stored at a temperature below 30.0 °C (111.6°F).

15 REGULATION INFORMATION

- 15.1 15.1 In Colombia: Must be stores in a fresh, dry place and protected from direct light heat and strong lighting. It should be stored at a temperature below 30.0 °C (111.6°F).
- 15.2 Keep out of the reach of children.
- 15.3 International: According to the acting regulations of each country.

16 OTHER IMPORTANT INFORMATION

In case of an emergency contact the Section of Physical and Industrial Safety at (574) 550 00 00.

The information provided in this safety data sheet is based in our current knowledge. No responsibility for the miss use of the product is assumed.

Created		Elaborated by:	Reviewed by:	
2011-10-05		Pharmaceutical Analyst	Quality Assurance Coordinator	
Class	Pages	Approved by:	Updated	Version
E	5 de 5	Anesthetics Technical Director	2019-05-31	3