MATERIAL SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION

Name: CITANEST® FORTE 4% INJECTION

Address/Phone No.: DENTSPLY Pharmaceutical
3427 Concord Road
York, PA 17402
Phone: 717-757-0200
800-225-2787

2. COMPOSITION/INFORMATION OR INGREDIENTS

Chemical Composition
Contains: Epinephrine bitartrate (0.0005%)
CAS No.: None assigned for the product
Use: local anesthetic for use in dental procedures

4.0 Prilocaine Hydrochloride  001786-81-8
0.05 Sodium Metabisulphite     007681-57-4

3. HAZARDS IDENTIFICATION

Form: liquid
Color: clear aqueous solution
Odor: odorless

As a result of the physical presentation of the product, the risk to health in the normal handling of the product is expected to be low.

4. FIRST AID MEASURES

Inhalation: Unlikely route of exposure. Remove patient from exposure. Obtain medical attention if ill effects occur.

Skin Contact: Remove contaminated clothing. Wash skin with soap and water. If symptoms (irritation or blistering) occur obtain medical attention.

Eye Contact: Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 15 minutes. Obtain medical attention.

Ingestion: Wash out mouth with water and give 200-300ml of water to drink. Do not induce vomiting. Obtain medical attention.

Note to Physicians
Symptomatic treatment and supportive therapy as indicated. For further detail consult the prescribing information.
5. **FIRE FIGHTING MEASURES**

**Flammable Properties**

If involved in a fire, it may burn and emit noxious and toxic fumes.

<table>
<thead>
<tr>
<th>Extinguishing Media</th>
<th>Foam, water, dry chemical or CO2.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fire Fighting Protective Equipment</td>
<td>A self-contained breathing apparatus and suitable protective clothing should be worn in fire conditions.</td>
</tr>
</tbody>
</table>

6. **ACCIDENTAL RELEASE MEASURES**

Ensure suitable personal protection during removal of spillages. Clear up spillages. Wash the spillage area with water. Transfer spilled vials to a suitable container for disposal. Take care to avoid needles and broken container.

7. **HANDLING AND STORAGE**

7.1 **HANDLING**

No special precautions are necessary when handling packed product. In case of accident, avoid contact with skin and eyes. Do not breathe mist.

7.2 **STORAGE**

Keep container tightly closed. Protect from light.

Storage Temperature : Keep at a temperature not exceeding (Deg C) 25.

8. **EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Engineering Controls**

No ACGIH TLV or OSHA PEL is assigned to this mixture.

<table>
<thead>
<tr>
<th>HAZAROUS INGREDIENT(S)</th>
<th>ppm</th>
<th>mg/m³</th>
<th>TWA ppm</th>
<th>mg/m³</th>
<th>STEL / CEILING (C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prilocaine hydrochloride</td>
<td>-</td>
<td>5</td>
<td>-</td>
<td>-</td>
<td>COM</td>
</tr>
<tr>
<td>Sodium Metabisulphite</td>
<td>-</td>
<td>5</td>
<td>-</td>
<td>-</td>
<td>TLV</td>
</tr>
</tbody>
</table>

This is an in-house standard for the active ingredient during manufacture.

**Personal Protective Equipment**

Wear suitable protective clothing

<table>
<thead>
<tr>
<th>Respirators</th>
<th>If needed, use NIOSH approved respirator for organic vapors, dusts and mists with a TLV greater than 0.05 mg/m³.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protective Clothing</td>
<td>If needed, impervious gloves and apron.</td>
</tr>
<tr>
<td>Eye Protection</td>
<td>Chemical tight goggles.</td>
</tr>
<tr>
<td>Other Protective Equipment</td>
<td>Eyewash station and safety shower in work area.</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

Form : liquid
Color : clear aqueous solution
Odor : odorless
pH (Value) : 3.3-5.5
Solubility (Water) : freely soluble
Specific Gravity : 1.007

10. STABILITY AND REACTIVITY

Stable under normal conditions.

Hazardous Reactions : Epinephrine is unstable in alkaline solutions when exposed to air or light.

Hazardous Decomposition Product(s) : None known.

11. TOXICOLOGICAL INFORMATION

The following information refers to active ingredient:

Inhalation : May cause tingling/numbness in exposed areas (paresthesia). Unlikely route of exposure. High atmospheric concentrations may lead to anesthetic effects.

Skin Contact : May cause mild skin irritation. Repeated and/or prolonged contact may cause skin sensitization in a small proportion of sensitive individuals.

Eye Contact : Risk of serious damage to eyes. May cause permanent damage if eye is not immediately irrigated.

Long Term Exposure : Chronic effects are unlikely.

12. ECOLOGICAL INFORMATION

No information of this formulation. The product is soluble in water. The following information refers to active ingredient:

Environmental Fate and Distribution

The substance has low potential for bioaccumulation.

Persistence and Degradation

May cause long-term adverse effects in the aquatic environment. Not readily biodegradable. (ISO7827-1984(E))

Toxicity

Harmful to aquatic organisms. LC50 (zebra fish) (96hour) 188mg/1. EC50 (Daphnia magna) (48 hour) 61mg/1. EC50 (green algae) (72 hour) 154mg/1.

Effect on Atmospheric Ozone

No information available.
13. DISPOSAL CONSIDERATIONS

Disposal should be in accordance with local, state or national legislation

Disposal Method : Epinephrine RCRA Code PO42.

14. TRANSPORT INFORMATION

Not classified as Dangerous for Transport.

15. REGULATORY INFORMATION

TSCA (Toxic Substances Control Act) Regulations, 40CFR 710: This product is a drug and is exempt from TSCA regulation. CERCLA and SARA Regulations (40CFR 355,370 and 372): This product does not contain any chemical subject to the reporting requirements of SARA Section 313. CERCLA/SUPERFUD: Contains reportable Quantity Substances, epinephrine and bisulfate. Other Determined Regulation: California Proposition 65: No warnings are necessary.

16. OTHER INFORMATION

This Material Safety Data Sheet was prepared in accordance with ANSI Standard Z400.1 1993, and modified 1998.

GLOSSARY

COM : The company aims to control exposure in its workplace to this limit
This is an in-house standard for the active ingredient handled during manufacture
TLV : The company aims to control exposure in its workplace to the ACGIH limit
Sk : Can be absorbed through skin
Sen : Capable of causing respiratory sensitization

The information herein is given in good faith but no warranty, expressed or implied, is made.

(Revision: 01 Date: 0300)

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