

# 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

**%(w/w) HAZARDOUS INGREDIENTS(S) CAS No.**

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.

Extinguishing Media : water spray, foam, dry chemical or CO<sub>2</sub>.  
Fire Fighting Protective Equipment : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

## 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.

HAZAROUS INGREDIENT(S)	ppm	mg/m <sup>3</sup>	TWA		STEL / CEILING (C)
			ppm	mg/m <sup>3</sup>	
Prilocaine hydrochloride	-	5	-	-	COM
This is an in-house standard for the active ingredient during manufacture.					
Sodium Metabisulphite	-	5	-	-	TLV

### Personal Protective Equipment

Wear suitable protective clothing

Respirators : If needed, use NIOSH approved respirator for organic vapors, dusts and mists with a TLV greater than 0.05 mg/m<sup>3</sup>.  
Protective Clothing : If needed, impervious gloves and apron.  
Eye Protection : Chemical tight goggles.  
Other Protective Equipment : Eyewash station and safety shower in work area.

## 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/l. EC50 (Daphnia magna) (48 hour) 61mg/l. EC50 (green algae) (72 hour) 154mg/l.

### 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.

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