

7-120-0054

MATERIAL SAFETY DATA SHEET**1. PRODUCT AND COMPANY IDENTIFICATION**

Name : CITANEST® SOLUTIONS FOR INJECTION

Address/Phone No.: DENTSPLY Pharmaceutical

3427 Concord Road
York, PA 17402
Phone: 717-757-0200
800-225-2787**Alternative Names**'Citanest' 0.5% Single Dose Vials
'Citanest' 0.5% Multi Dose Vials
'Citanest' 1% Multi Dose Vials
'Citanest' 2% Solution
'Citanest' Plain 4% Injection
'Citanest' 4% Solution for Injection**2. COMPOSITION/INFORMATION ON INGREDIENTS**

CAS No. : None assigned for the product

Use : Local anesthetic solution for use in infiltration anesthesia, intravenous regional anesthesia and nerve blocks.

%(w/w) **HARDOUS INGREDIENT(S)** CAS No.

0.5-4.0 Prilocaine Hydrochloride 001786-81-8

3. HAZARDS IDENTIFICATIONForm : 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 MEASURESInhalation : 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 CO₂.
 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 containers.

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.
 Storage Life : 3 years

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Engineering Controls**

No ACGIH TLV or OSHA PEL as assigned.

HAZARDOUS INGREDIENT(S)	TWA		STEL /CEILING (C)	
	ppm	mg/m ³	ppm	mg/m ³
Prilocaine hydrochloride This is an in-house standard for the active ingredient during manufacture.	5	-	-	COM

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/m³.

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) : 6.0-7.0
Solubility (Water) : freely soluble
Specific Gravity : 1.007

10. STABILITY AND REACTIVITY

Stable under normal conditions.

Hazardous Reactions : Incompatible materials: Water reactive materials.
Hazardous Decomposition Product(s) : None known.

11. TOXICOLOGICAL INFORMATION

The following information refers to active ingredient:

Inhalation : Unlikely route of exposure. May cause tingling/numbness in exposed areas (paresthesia). 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.
Ingestion : By analogy with a similar substance this material is likely to be harmful. Lidocaine: Oral Median Lethal Dose 317mg/kg (rat). May produce numbness of the tongue and anesthetic effects on the stomach.
Long Term Exposure : Chronic effects are unlikely.

12. ECOLOGICAL INFORMATION

No information on 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. (ISO 7827-1984(E))

Toxicity

Harmful to aquatic organisms. LC50 (zebra fish) (96 hour) 138mg/l. EC50(Daphnia magna) (48 hour) 61 mg/l. EC50 (green algae) (72 hour) 154mg/l.

Effect on Effluent Treatment

No information available.

13. DISPOSAL CONSIDERATIONS

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

Container Disposal : Empty container retains product residue. Observe all hazard precautions.

14. TRANSPORT INFORMATION

Not Classified as Dangerous for Transport.

15. REGULATORY INFORMATION

TSCA (Toxic Substance Control Act) Regulations, 40 CFR 710: This product is a drug and is exempt from TSCA regulation. CERCLA AND SARA Regulations (40 CFR 355,370, and 372): This product does not contain any chemicals subject to the reporting requirements of SARA Section 313. Other Determined Regulations: 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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