

# MATERIAL SAFETY DATA SHEET

## 1. PRODUCT AND COMPANY IDENTIFICATION

**Name:** XYLOCAINE® SOLUTIONS WITH EPINEPHRINE

**Address/Phone No.:** DENTSPLY Pharmaceutical

3427 Concord Road  
York, PA 17402  
Phone: 717-757-0200  
800-225-2787

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Chemical Composition

Contains: adrenaline/epinephrine (0.0005-0.001%)

CAS No.: None assigned for the product

Use : Local anesthetic solution for use in infiltration anesthesia, peripheral and Central nerve blocks.

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

0.5-2.0 Lidocaine hydrochloride 000073-78-9

## 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 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 : between 2-8 Deg C

Storage Life : Total storage life at recommended conditions: 2 year(s)

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Engineering Controls

No ACGIH TLV or OSHA PEL assigned.

HAZARDOUS INGREDIENT(S)	ppm	TWA mg/m <sup>3</sup>	ppm	STEL mg/m <sup>3</sup>	/CEILING (C)
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Lidocaine hydrochloride	—	4	—	—	COM
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This is an in-house standard for the active ingredient during manufacture.

### 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 SHEMICAL PROPERTIES

Form : liquid  
Color : clear aqueous solution  
Odor : odorless  
Vapor Pressure (mmHg) : 17 at 20 Deg C  
Solubility (Water) : soluble  
Specific Gravity : 1 approx.  
Vapor Density (Air = 1) : 0.6

## 10. STABILITY AND REACTIVITY

Stable under normal conditions.

Hazardous Reactions : Incompatible materials: Water reactive materials. 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 : Unlikely route of exposure. May cause tingling/numbness in exposed areas (paresthesia). High atmospheric concentrations may lead to anesthetic effects. May produce a reduced heart rate and reduction in blood pressure with a resulting feeling of dizziness.

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

Eye Contact : May cause excessive watering of the eye (lacrimation).

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 : Repeated exposure of animals to high levels produces adverse effects on the : liver, central nervous system.

## 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

Not readily biodegradable. (ISO 7827-1984(E))

## **Toxicity**

Low toxicity to aquatic organisms. LC50 (zebra fish) (96 hour) 106mg/1. EC50 (Daphnia magna) (48hour) 112mg/1. EC50 (green algae) (72 hour)780mg/1. EC50 (Microtox test) (15 minutes) >1000mg/1.

## **Effect on Effluent Treatment**

No information available.

## **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, 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. CERCLA/SUPERFUND: Contains Reportable Quantity Substance-epinephrine. 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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**(US00)**

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