

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 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 : 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)	TWA ppm	STEL mg/m³	/CEILING (C) mg/m³
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Lidocaine hydrochloride – 4 – COM

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/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 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/l. EC50 (Daphnia magna) (48hour) 112mg/l. EC50 (green algae) (72 hour) 780mg/l. EC50 (Microtox test) (15 minutes) >1000mg/l.

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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