

Dentsply Pharmaceutical

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SECTION 1 : CHEMICAL PRODUCT AND COMPANY IDENTIFICATION  
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MSDS Name: ~~Xylocaine Injections~~  
Manufacturer Name: Dentsply Pharmaceutical  
Address:  
3427 Concord Road  
York, PA 17402  
Business Phone: 717-757-0200; 800-225-2787  
For information in North America, call: 717-757-0200; 800-225-2787  
Manufacturer MSDS Revision Date: 0200  
Supersedes: 9/01

Revision: 01

General Use:

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

Alternative Names:

Lidocaine for injection  
Lignocaine for injection  
'Xylocaine' Plain

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SECTION 2 : COMPOSITION, INFORMATION ON INGREDIENTS  
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Chemical Name  
Lidocaine hydrochloride CAS#  
000073-78-9 % Weight  
0.5-5.0%

Hazardous: Yes

CAS No.:

None assigned for the product

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

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SECTION 3 : HAZARDS IDENTIFICATION  
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Physical State:

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.

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SECTION 4 : FIRST AID MEASURES  
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Eye Contact:

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

Skin Contact:

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

Inhalation:

Remove patient from exposure. Obtain medical attention if ill effects occur.

Ingestion:

Wash out mouth with water and give 200-300 ml. 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.

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SECTION 5 : FIRE FIGHTING MEASURES  
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Fire:

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.

Protective Equipment:

Fire Fighting: A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

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SECTION 6 : ACCIDENTAL RELEASE MEASURES  
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Spill Cleanup Measures:

Ensure suitable personal protection during removal of spillages. Clean 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.

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SECTION 7 : HANDLING and STORAGE  
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Handling:

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

Storage:

Keep container tightly closed. Protect from light.

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

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SECTION 8 : EXPOSURE CONTROLS, PERSONAL PROTECTION  
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Engineering Controls:

No ACGIH TLV or OSHA PEL assigned.

Personal Protective Equipment

Routine Handling:

Wear suitable protective clothing.

Eye/Face Protection:

Chemical tight goggles.

Protective Clothing/Body Protection:

If needed, impervious gloves and apron.

Respiratory Protection:

If needed, use NIOSH approved respirator for organic vapors, dusts and mists with a TLV greater than 0.05 mg/m<sup>3</sup>.

Other Protective:

Eyewash station and safety shower in work area.

Exposure Limits:

HAZARDOUS INGREDIENT(S): Lidocaine hydrochloride

TWA: 4 mg/m<sup>3</sup>

CEILING (C): COM

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

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SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES  
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Physical State/Appearance:

Form: Liquid

Color:

Clear aqueous solution

Odor:

Odorless

pH:

(Value): 6.5

Vapor Pressure:

(mm Hg): 17 at 20 Deg C

Vapor Density:

(Air = 1): 0.6

Solubility:

(Water): Soluble

Specific Gravity:

1.007

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SECTION 10 : STABILITY AND REACTIVITY  
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Chemical Stability:

Stable under normal conditions.

Incompatibilities with Other Materials:

Water reactive materials.

Hazardous Decomposition Products:

None known.

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SECTION 11 : TOXICOLOGICAL INFORMATION  
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Lidocaine hydrochloride:

Eye Effect:

May cause excessive watering of the eye (lacrimation).

Skin Effects:

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

Ingestion Effects:

By analogy with a similar substance this material is likely to be harmful. Lidocaine: Oral Median Lethal Dose 317 mg/kg (rat). May produce numbness of the tongue and anesthetic effects on the stomach.

Inhalation Effects:

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.

Chronic Effects:

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

The above information refers to active ingredient.

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SECTION 12 : ECOLOGICAL INFORMATION  
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Ecological Paragraph:

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

Environmental Fate:

Distribution: The substance has low potential for bioaccumulation.

Effect of Material on Plants/Animals:

Toxicity:

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

Persistence and Degradation:

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

Effect on Effluent Treatment: No information available.

Effect on Atmospheric Ozone: No information available.

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SECTION 13 : DISPOSAL CONSIDERATIONS  
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Waste Disposal:

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

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

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SECTION 14 : TRANSPORT INFORMATION  
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Transportation Information:  
Not Classified as Dangerous for Transport.

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SECTION 15 : REGULATORY INFORMATION  
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Applies to all ingredients:  
TSCA 8(b): Inventory Status  
TSCA (Toxic Substance Control Act) Regulations, 40 CFR 710: This product is a drug and is exempt from TSCA regulation.  
Section 304:  
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 Toxic Release Form:  
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.  
State:  
California Proposition 65: No warnings are necessary.

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SECTION 16 : ADDITIONAL INFORMATION  
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MSDS Revision Date:  
0200  
Supersedes: 9/01

Revision: 01  
Disclaimer:

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

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

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

(US00)

(PH1394)

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