

364

13924
30963

362
12704

366



Astra Pharmaceutical Products, Inc.
50 Otis Street, Westborough, MA 01581 • Tel. 508-366-1100

MATERIAL SAFETY DATA SHEET

PRODUCT NAME

Xylocaine Solutions with Epinephrine

CHEMTREC® Emergency Telephone Numbers (24-HOURS):
United States: 1-800/424-9300
International: 302/483-7616 (collect)
These CHEMTREC® numbers are to be used ONLY IN THE EVENT OF A CHEMICAL EMERGENCY INVOLVING A SPILL, LEAK, FIRE, EXPOSURE OR ACCIDENT.

GENERAL INFORMATION PHONE NO.
1-508-366-1100

DATE THIS FORM PREPARED
September 1, 1987

SIGNATURE OF CERTIFYING COMPANY OFFICIAL
[Signature]

1. MATERIAL AND MANUFACTURER IDENTIFICATION

| | |
|-----------------------------|--|
| SYNONYM(S) / CLASSIFICATION | Aqueous solutions of Xylocaine (Lidocaine hydrochloride) and epinephrine as pharmaceutical products. |
| PRODUCT USE | Local anesthetic products for use by injection. |
| MANUFACTURER NAME & ADDRESS | ASTRA Pharmaceutical Products, Inc. 50 Otis Street, Westborough, MA 01581 |

2. REGULATORY INFORMATION

| | | |
|---|--|-----------------------------|
| DOT (HMTA) DEPARTMENT OF TRANSPORTATION | Not listed as a hazardous material | U.S. OR H.A. NUMBER None |
| EPA (CERCLA/RCRA) ENVIRONMENTAL PROTECTION AGENCY | Not listed as a hazardous substance (see comments on page 3) | |
| OSHA (OSHA) OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION | Not listed as a hazardous chemical | |
| EPA (TSCA) ENVIRONMENTAL PROTECTION AGENCY | Not listed as a hazardous chemical substance | |

3. HAZARDOUS INGREDIENTS

| NAME | CAS NUMBER | % CONC. | OSHA PEL | ACGIH TLV | OTHER |
|-------------------------|------------|-----------------|------------|------------|------------|
| Lidocaine hydrochloride | 73-78-9 | 0.5 to 2.0 | Not listed | Not listed | Not listed |
| Epinephrine | 51-43-4 | 0.0005 or 0.001 | Not listed | Not listed | Not listed |

4. PHYSICAL DATA

| | | | |
|-----------------------------|-----------------|------------------------------|---------|
| BOILING RANGE (°C) | ~100 | SOLUBILITY IN WATER | Soluble |
| MELTING POINT (°C) | ~ 0 | SPECIFIC GRAVITY (water = 1) | ~ 1 |
| VAPOR PRESSURE (mm Hg)@20°C | ~17 | EVAPORATION RATE (water = 1) | ~ 1 |
| VAPOR DENSITY (air = 1) | 0.6 | PHYSICAL STATE | Liquid |
| COLOR AND ODOR | Clear, odorless | | |

5. FIRE AND EXPLOSION HAZARD DATA

| | | |
|--|----------------|---|
| FLASH POINT (AND METHOD USED) | Not flammable | FLAMMABLE LIMITS (STP) LOWER: N.A. UPPER: N.A. |
| EXTINGUISHING MEDIA | Not applicable | |
| SPECIAL FIRE FIGHTING PROTECTIVE EQUIPMENT | None | |
| UNUSUAL FIRE AND EXPLOSION HAZARDS | None | |

6. REACTIVITY DATA

| | | | |
|--------------------------------------|---|-------------------------------------|-----------------------------|
| STABILITY | STABLE | <input checked="" type="checkbox"/> | CONDITIONS TO AVOID None |
| | UNSTABLE | <input type="checkbox"/> | |
| INCOMPATIBILITY (MATERIALS TO AVOID) | Compounds which react violently with water. | | |
| HAZARDOUS DECOMPOSITION PRODUCTS | None | | |
| HAZARDOUS POLYMERIZATION | MAY OCCUR | <input type="checkbox"/> | CONDITIONS TO AVOID None |
| | WILL NOT OCCUR | <input checked="" type="checkbox"/> | |

| | | | | |
|---|---|--------|------------------------------------|------------|
| HAZARD CLASSIFICATION BASED ON NFPA SYSTEM | HAZARD CODE 4: EXTREME 3: HIGH 2: MODERATE 1: SLIGHT 0: NEGLIGIBLE | HEALTH | <p>FLAMMABILITY</p> <p>SPECIAL</p> | REACTIVITY |
| | | | | |

7. SPECIAL PROTECTION INFORMATION

| | |
|--|--|
| VENTILATION | LOCAL EXHAUST <input checked="" type="checkbox"/> MECHANICAL (General) <input type="checkbox"/> SPECIAL <input type="checkbox"/> |
| RESPIRATORY PROTECTION (Specify Type) | None normally required |
| PROTECTIVE CLOTHING | None normally required |
| EYE PROTECTION | None normally required |
| OTHER PROTECTIVE EQUIPMENT | None normally required. |
| WORKHYGIENIC PRACTICES | Avoid ingestion and contact with eyes. |

8. SPILL OR LEAK PROCEDURES

| | |
|---|--|
| STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED | Clean up spills with normal procedures used for non-hazardous liquids. |
| DISPOSAL METHOD | Dispose as a non-hazardous waste. |

9. SPECIAL PRECAUTIONS

| | |
|--------------------------------------|--|
| HANDLING AND STORING REQUIREMENTS | Store in a cool, dry place. Avoid extremes in temperature. Handle to avoid breakage. |
| PRECAUTIONARY LABELING | None required. Caution against ingestion and contact with the eyes is recommended. |

COMMENTS:

Data and information for items 4 through 9 relate to the products as a whole (aqueous solutions). Epinephrine is listed as a hazardous substance in the RCRA (EPA) and CERCLA (EPA) regulations. However, the concentrations of epinephrine in these products are very low (1:200,000 ; 1:100,000).

10. HEALTH HAZARD DATA

| | |
|---|---|
| POTENTIAL CONTACT AND ROUTES OF ENTRY | INHALATION <input type="checkbox"/> INGESTION <input checked="" type="checkbox"/> SKIN <input checked="" type="checkbox"/> EYE <input checked="" type="checkbox"/> |
| BASIS OF HEALTH HAZARD DETERMINATION | PRODUCT AS A WHOLE <input checked="" type="checkbox"/> INDIVIDUAL CONSTITUENTS <input type="checkbox"/> |
| HEALTH HAZARDS | <p>Ingestion and systemic absorption of these products may result in toxic effects on the central nervous system and on the cardiovascular system. Allergic reactions may also occur.</p> <p>Significant adverse effects on intact skin are unlikely. Contact with mucous membranes may cause irritation plus numbness and loss of sensation.</p> <p>Contact with the eye may cause irritation. Eye contact will also cause numbness and loss of sensation.</p> |
| SIGNS AND SYMPTOMS OF EXPOSURE | Systemic effects may include nervousness, confusion, drowsiness, blurred vision, vomiting, tremors, convulsions, respiratory depression, slowing of the heart, blood pressure drop, and unconsciousness. |
| EMERGENCY AND FIRST AID PROCEDURES | Call a physician. Medical attention should include maintenance of breathing and controlling convulsions if they occur. If eye contact occurs, wash thoroughly with clean water for 15 minutes. |
| MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE | Hypersensitivity to local anesthetics of the amide type. |
| CARCINOGENICITY | NOT LISTED <input checked="" type="checkbox"/> NTP <input type="checkbox"/> IARC <input type="checkbox"/> OSHA <input type="checkbox"/> |

COMMENTS:

Lidocaine hydrochloride is a local anesthetic agent, and like all local anesthetics it can depress excitable tissues. Thus, it may cause adverse effects on the nervous system, on respiration, and on the cardiovascular system.