

BEGIN MSDS ESIPB104

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SECTION 1 CHEMICAL PRODUCT AND COMPANY IDENTIFICATION  
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ESI-LEDERLE GENERICS  
P.O. Box 8299  
Philadelphia, PA 19101  
610-688-4400

24 HR. Emergency Medical Information:  
610-688-4400  
CHEMTREC(R) USA, CAN, PR: 800-424-9300  
International: 202-483-7616

SUBSTANCE: HEPARIN

TRADE NAMES/SYNONYMS:  
HEPARIN SODIUM INJECTION; ESIPB104

PRODUCT USE: pharmaceutical

CREATION DATE: Nov 01 1991  
REVISION DATE: Apr 16 2001

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SECTION 2 COMPOSITION, INFORMATION ON INGREDIENTS  
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COMPONENT: HEPARIN SODIUM  
CAS NUMBER: 9041-08-1  
EC NUMBER: Not assigned.  
PERCENTAGE: 0.7-7

COMPONENT: BENZYL ALCOHOL  
CAS NUMBER: 100-51-6  
EC NUMBER (EINECS): 202-859-9  
PERCENTAGE: 1

COMPONENT: WATER  
CAS NUMBER: 7732-18-5  
EC NUMBER (EINECS): 231-791-2  
PERCENTAGE: >1

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SECTION 3 HAZARDS IDENTIFICATION  
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NFPA RATINGS (SCALE 0-4): HEALTH=1 FIRE=1 REACTIVITY=0

EMERGENCY OVERVIEW:  
PHYSICAL DESCRIPTION: Clear solution.  
MAJOR HEALTH HAZARDS: No significant target effects reported.

POTENTIAL HEALTH EFFECTS:

INHALATION:

SHORT TERM EXPOSURE: no information is available

LONG TERM EXPOSURE: no information is available

SKIN CONTACT:

SHORT TERM EXPOSURE: no information on significant adverse effects

LONG TERM EXPOSURE: no information is available

EYE CONTACT:

SHORT TERM EXPOSURE: no information is available  
LONG TERM EXPOSURE: no information on significant adverse effects  
INGESTION:  
SHORT TERM EXPOSURE: no information on significant adverse effects  
LONG TERM EXPOSURE: no information is available

CARCINOGEN STATUS:  
OSHA: No  
NTP: No  
IARC: No

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SECTION 4 FIRST AID MEASURES

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INHALATION: If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. Get immediate medical attention.

SKIN CONTACT: Wash skin with soap and water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention, if needed. Thoroughly clean and dry contaminated clothing and shoes before reuse.

EYE CONTACT: Flush eyes with plenty of water for at least 15 minutes. Then get immediate medical attention.

INGESTION: If a large amount is swallowed, get medical attention.

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SECTION 5 FIRE FIGHTING MEASURES

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FIRE AND EXPLOSION HAZARDS: Slight fire hazard.

EXTINGUISHING MEDIA: regular dry chemical, carbon dioxide, water, regular foam

Large fires: Use regular foam or flood with fine water spray.

FIRE FIGHTING: Move container from fire area if it can be done without risk.

Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

FLASH POINT: >214 F (>101 C)  
FLAMMABILITY CLASS (OSHA): IIIIB

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SECTION 6 ACCIDENTAL RELEASE MEASURES

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OCCUPATIONAL RELEASE:

Do not touch spilled material. Avoid heat, flames, sparks and other sources of ignition. Remove sources of ignition. Absorb with sand or other non-combustible material. Collect spilled material in appropriate container for disposal.

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SECTION 7 HANDLING AND STORAGE

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STORAGE: Store and handle in accordance with all current regulations and standards. Keep separated from incompatible substances. See original container for storage recommendations.

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SECTION 8 EXPOSURE CONTROLS, PERSONAL PROTECTION

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EXPOSURE LIMITS:

BENZYL ALCOHOL:

10 ppm AIHA recommended TWA

VENTILATION: Under normal conditions of use, no special ventilation equipment is needed.

EYE PROTECTION: Eye protection not required, but recommended.

CLOTHING: Under normal conditions of use, wear suitable clothing to prevent contact with skin.

GLOVES: Wear appropriate chemical resistant gloves.

RESPIRATOR: No respirator is required under normal conditions of use. Under conditions of frequent use or heavy exposure, respiratory protection may be needed.

Respiratory protection is ranked in order from minimum to maximum.

Consider warning properties before use.

Any dust and mist respirator.

Any air-purifying respirator with a high-efficiency particulate filter.

For Unknown Concentrations or Immediately Dangerous to Life or Health -

Any supplied-air respirator with a full facepiece that is operated in a pressure-demand or other positive-pressure mode.

Any self-contained breathing apparatus.

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SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

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PHYSICAL DESCRIPTION: Clear solution.

BOILING POINT: Not available

FREEZING POINT: Not available

VAPOR PRESSURE: Not available

VAPOR DENSITY: Not available

SPECIFIC GRAVITY: Not available

WATER SOLUBILITY: soluble

PH: 5.0-7.5

VOLATILITY: Not available

ODOR THRESHOLD: Not available

EVAPORATION RATE: Not available

COEFFICIENT OF WATER/OIL DISTRIBUTION: Not available

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SECTION 10 STABILITY AND REACTIVITY

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REACTIVITY: Stable at normal temperatures and pressure.

CONDITIONS TO AVOID: Avoid heat, flames, sparks and other sources of ignition.  
Avoid contact with incompatible materials.

INCOMPATIBILITIES:

May be incompatible with acids, bases, and oxidizers.

HAZARDOUS DECOMPOSITION:

Thermal decomposition products: miscellaneous decomposition products

POLYMERIZATION: Will not polymerize.

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SECTION 11 TOXICOLOGICAL INFORMATION  
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HEPARIN SODIUM:

TOXICITY DATA:

943 mg/kg/47 week(s) intermittent subcutaneous-man TDLo; 3400 units/kg/17 day(s) intermittent subcutaneous-woman TDLo; 7 mg/kg/4 day(s) subcutaneous-man TDLo; 1400 units/kg/1 week(s) intermittent subcutaneous-woman TDLo; 700 units/kg/13 day(s) intermittent intravenous-woman TDLo; >779000 iu/kg oral-rat LD50; 46715 iu/kg subcutaneous-rat LD50; 391821 iu/kg intravenous-rat LD50; >5 gm/kg oral-mouse LD50; >2500 mg/kg intraperitoneal-mouse LD50; >2500 mg/kg subcutaneous-mouse LD50; 2800 mg/kg intravenous-mouse LD50; 2800 mg/kg unreported-mouse LD50; 1 gm/kg intravenous-dog LD50; 84 ku/kg/28 day(s) intermittent intravenous-rat TDLo

ACUTE TOXICITY LEVEL: Insufficient Data.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: high blood pressure, blood system disorders, gastrointestinal disorders, heart problems, kidney disorders, liver disorders

ADDITIONAL DATA: Interactions with drugs may occur.

Heparin sodium is an anticoagulant drug. Therapeutic parenteral administration may cause hemorrhages at any site, hypersensitivity reactions, thrombocytopenia possibly leading to severe thromboembolic complications including skin necrosis, gangrene requiring amputation, myocardial infarction, pulmonary embolism, stroke and death. Renal dysfunction, osteoporosis and subsequent spontaneous fractures may occur following prolonged high doses. Other reported effects include suppression of aldosterone synthesis, delayed transient alopecia, priapism, and rebound hyperlipemia. Heparin does not cross the placenta and has not been associated with fetal malformations. However, fetal mortality or prematurity has occurred in about one third of pregnancies where heparin was administered.

HEALTH EFFECTS:

INHALATION:

ACUTE EXPOSURE:

HEPARIN SODIUM: No data available.

CHRONIC EXPOSURE:

HEPARIN SODIUM: No data available.

SKIN CONTACT:

ACUTE EXPOSURE:

HEPARIN SODIUM: Absorption may occur through damaged skin.

CHRONIC EXPOSURE:  
HEPARIN SODIUM: No data available.

EYE CONTACT:  
ACUTE EXPOSURE:  
HEPARIN SODIUM: No data available.

CHRONIC EXPOSURE:  
HEPARIN SODIUM: Repeated application of a 5% solution in water to rabbit eyes produced no injury. However, a 30% solution injured the corneal epithelium only slightly.

INGESTION:  
ACUTE EXPOSURE:  
HEPARIN SODIUM: Heparin sodium is reported to be inactive and unabsorbed following oral administration.  
  
CHRONIC EXPOSURE:  
HEPARIN SODIUM: No data available.

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SECTION 12 ECOLOGICAL INFORMATION

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Not available

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SECTION 13 DISPOSAL CONSIDERATIONS

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Dispose in accordance with all applicable regulations.

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SECTION 14 TRANSPORT INFORMATION

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U.S. DEPARTMENT OF TRANSPORTATION: No classification assigned.

CANADIAN TRANSPORTATION OF DANGEROUS GOODS: No classification assigned.

LAND TRANSPORT ADR/RID: No classification assigned.

AIR TRANSPORT IATA/ICAO: No classification assigned.

MARITIME TRANSPORT IMDG: No classification assigned.

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SECTION 15 REGULATORY INFORMATION

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U.S. REGULATIONS:  
CERCLA SECTIONS 102a/103 HAZARDOUS SUBSTANCES (40 CFR 302.4): Not regulated.

SARA TITLE III SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.30):  
Not regulated.

SARA TITLE III SECTION 304 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.40):

Not regulated.

SARA TITLE III SARA SECTIONS 311/312 HAZARDOUS CATEGORIES (40 CFR 370.21):

ACUTE: No  
CHRONIC: No  
FIRE: No  
REACTIVE: No  
SUDDEN RELEASE: No

SARA TITLE III SECTION 313 (40 CFR 372.65): Not regulated.

OSHA PROCESS SAFETY (29CFR1910.119): Not regulated.

STATE REGULATIONS:

California Proposition 65: Not regulated.

CANADIAN REGULATIONS:

WHMIS CLASSIFICATION: Not determined.

EUROPEAN REGULATIONS:

EC CLASSIFICATION (CALCULATED): Not determined.

NATIONAL INVENTORY STATUS:

U.S. INVENTORY (TSCA): Exempt.

TSCA 12(b) EXPORT NOTIFICATION: Not listed.

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SECTION 16 OTHER INFORMATION  
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