MATERIAL SAFETY DATA SHEET

Product Name: Heparin Sodium Injection, USP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone **Hospira, Inc., Non-Emergency**	CHEMTREC: North America: 800-424-9300; International: 1-703-527-3887 224 212-2055
Product Name	Heparin Sodium Injection, USP
Synonyms	None

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Heparin Sodium
Chemical Formula Heparin is an acidic, polymeric mucopolysaccharide composed of units of glucuronic acid and sulfated glucosamine

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Heparin Sodium	< 7.0%	9041-08-1	MI0850000
Benzyl Alcohol	1.0	100-51-6	DN3150000

Non-hazardous ingredients include water. Hazardous ingredients present at less than 1% include sodium chloride; sodium hydroxide and/or hydrochloric acid which are used to adjust the pH.

3. HAZARD INFORMATION

Emergency Overview Heparin Sodium Injection, USP, is a solution containing heparin sodium, a heterogenous group of straight-chain anionic mucopolysaccharides, called glycosaminoglycans, having anticoagulant properties. This product is used clinically as an anti-coagulant. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the blood and liver.

Occupational Exposure Potential Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms No signs or symptoms from occupational exposure are known. Based on clinical use, adverse effects may include hemorrhage, prolongation of coagulation test times, increased susceptibility to bruising, bleeding, decreases in thrombocytes, and elevation in liver function parameters. Significant elevations of liver enzyme levels have occurred in a high percentage of patients (and healthy subjects) who have received heparin. Less frequently, allergic hypersensitivity reactions to heparin have occurred. Local irritation, erythema, mild pain, hematoma, or ulceration can occur after deep subcutaneous injection or intramuscular injection.

Medical Conditions Aggravated by Exposure Hypersensitivity to the heparin sodium and/or similar materials. Pre-existing hematopoietic system or liver ailments.

Carcinogen Lists: **IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed

4. FIRST AID MEASURES

Eye Contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Skin Contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Inhalation	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Ingestion	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary

5. FIRE FIGHTING MEASURES

Flammability	None anticipated for this aqueous product.
Fire & Explosion Hazard	None anticipated for this aqueous product.
Extinguishing Media	As with any fire, use extinguishing media appropriate for primary cause of fire.
Special Fire Fighting Procedures	No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal	Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling	No special handling required under conditions of normal product use.
Storage	No special storage required for hazard control. For product protection, follow USP controlled room temperature storage recommendations noted on the product case label, the primary container label, or the product insert.
Special Precautions	None required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
Heparin Sodium	8 hr TWA: Not Established	8 hr TWA: Not Established	8-hr TWA: Not Established	8 hr TWA: 500 mcg/m3 STEL: Not Established
Benzyl Alcohol	8 hr TWA: Not Established	8 hr TWA: Not Established	8-hr TWA: 10 ppm	8 hr TWA: Not Established STEL: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.

Respiratory Protection Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin Protection If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye Protection Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Clear, colorless to practically colorless solution
Odor	NA
Odor Threshold:	NA
pH:	5.0-7.5
Melting point/Freezing point:	NA
Initial Boiling Point/Boiling Point Range	NA
Evaporation Rate:	NA
Flammability (solid, gas):	NA
Upper/Lower Flammability or Explosive Limits:	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Evaporation Rate	NA
Bulk Density	1.007-1.036 g/mL
Specific Gravity	1.01-1.039 at 25°C
Solubility	NA
Partition coefficient: n-octanol/water:	NA
Auto-ignition temperature	NA
Decomposition temperature	NA

10. STABILITY AND REACTIVITY

Reactivity Not determined.

Chemical Stability Stable under standard use and storage conditions.

Hazardous Reactions Not determined

Conditions to avoid Not determined

Incompatibilities Not determined

Hazardous Decomposition Products Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).

Hazardous Polymerization Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Heparin Sodium	100	LD50	Oral	>5770 >5000	mg/kg mg/kg	Rat Mouse
Heparin Sodium	100	LD50	Intravenous	2902 2800 1000	mg/kg mg/kg mg/kg	Rat Mouse Dog
Heparin Sodium	100	LD50	Intraperitoneal	>2500	mg/kg	Mouse
Benzyl Alcohol	100	LD50	Oral	1230 1360 1040	mg/kg mg/kg mg/kg	Rat Mouse, Rabbit
Benzyl Alcohol	100	LD50	Dermal	2000	mg/kg	Rabbit
Benzyl Alcohol	100	LC50	Inhalation	> 500	mg/m3	Rat, Mouse

LD50: Dosage that produces 50% mortality.
LC50 is the concentration in air that produces 50% mortality when inhaled.

Aspiration Hazard None anticipated from normal handling of this product.

Dermal Irritation/Corrosion None anticipated from normal handling of this product.

Ocular Irritation/Corrosion None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce redness and discomfort.

Dermal or Respiratory Sensitization None anticipated from normal handling of this product. In clinical use, allergic hypersensitivity reactions to heparin have occurred.

Reproductive Effects Studies to evaluate the effects of heparin on fertility or fetal development have not been conducted in animals.

Mutagenicity Studies to evaluate the genotoxic potential of heparin have not been conducted.

Carcinogenicity Studies to evaluate the effects of heparin on fertility or fetal development have not been conducted in animals.

Target Organ Effects Based on clinical use, possible target organs include the blood and liver.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity	Not determined for product. Information for ingredients is provided below: LC50(96 hr) = 460 mg/L in Pimephales promelas for benzyl alcohol LC50 = 640 mg/L in Leuciscus idus for benzyl alcohol EC50(24 hr) = 400 mg/L in Daphnia magna for benzyl alcohol EC50 = 95 mg/L in Chlorella pyrenoidosa for benzyl alcohol
Persistence/Biodegradability	Not determined for the product. Information for ingredients is provided below: Benzyl alcohol was degraded over 90% in a 28-day biodegradation assay in sewage sludge.
Bioaccumulation	Not determined for product.
Mobility in Soil	Not determined for product.

Notes:
1. EC50: Concentration in water that produces 50% mortality in Daphnia sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EC50: Concentration in water that produces 50% inhibition of growth in algae.

13. DISPOSAL CONSIDERATIONS

Waste Disposal	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

DOT STATUS:	Not regulated
Proper Shipping Name:	NA
Hazard Class:	NA
UN Number:	NA
Packing Group:	NA
Reportable Quantity:	NA
ICAO/IATA STATUS	Not regulated
Proper Shipping Name:	NA
Hazard Class:	NA
UN Number:	NA
Packing Group:	NA
Reportable Quantity:	NA
IMDG STATUS	Not regulated
Proper Shipping Name:	NA
Hazard Class:	NA
UN Number:	NA
Packing Group:	NA
Reportable Quantity:	NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

TSCA Status	Exempt. However, heparin sodium is listed on the TSCA inventory.
CERCLA Status	Not listed
SARA 302 Status	Not listed
SARA 313 Status	Not listed
RCRA Status	Not listed
PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

U.S. OSHA Classification Possible Irritant
Target Organ Toxin

GHS Classification *Where medicinal products are not exempt, the recommended GHS workplace classification is as follows:

Hazard Class	Acute Oral Toxicity	Eye Irritation	Target Organ Toxicity
Hazard Category	Not Classified	2B	2
Symbol	NA	NA	
Signal Word	NA	Warning	Warning
Hazard Statement	NA	Causes eye irritation	May cause damage to the hematopoietic system and liver through prolonged or repeated exposure.

Prevention: Do not breathe vapor or spray.

Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell.

15. REGULATORY INFORMATION: continued

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance heparin sodium.

Classification(s): Irritant

Symbol:

Indication of Danger Xi

Risk Phrases: R36/37 - Irritating to eyes and respiratory system

Safety Phrases: S23: Do not breathe vapor/spray
S24: Avoid contact with the skin
S25: Avoid contact with eyes
S37/39 Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD_{50}	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator:	Global Occupational Toxicology
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