



## MATERIAL SAFETY DATA SHEET

**Product Name: Heparin Lock Flush Solution, USP**

### 1. CHEMICAL PRODUCT AND COMPANY INFORMATION

**Manufacturer Name And Address** Hospira Inc.  
275 North Field Drive  
Lake Forest, Illinois USA  
60045

**Emergency Telephone** CHEMTREC: North America: 800-424-9300;  
International 1-703-527-3887; Australia (02) 8014 4880

**Hospira, Inc., Non-Emergency** 224-212-2000

**Product Name** Heparin Lock Flush Solution, USP

**Synonyms** Multi-Dose Fliptop Vials

### 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

**Preparation** Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include sodium chloride, edetate disodium and benzyl alcohol; sodium hydroxide is used to adjust the pH.

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Heparin Sodium	0.1	9041-08-1	MI0850000

### 3. HAZARD INFORMATION

#### Carcinogen List

Substance	IARC	NTP	OSHA
Heparin Sodium	Not Listed	Not Listed	Not Listed

**Emergency Overview** Heparin Lock Flush Solution, USP, is a solution containing heparin sodium, a heterogenous group of straight-chain anionic mucopolysaccharides, called glycosaminoglycans. Clinically, this product is used 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

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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.

### 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 for hazard control under conditions of normal product use.

**Storage** No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

**Special Precautions** No special precautions required for hazard control.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Exposure Guidelines**

Component	Type	Exposure limits			
		mg/m <sup>3</sup>	ppm	µg/m <sup>3</sup>	Note
Heparin Sodium	Hospira EEL	N/A	N/A	500	8hr TWA

**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**

<b>Appearance/Physical State</b>	Liquid
<b>Color</b>	Clear, Colorless to practically colorless.
<b>Odor</b>	NA
<b>Odor Threshold:</b>	NA
<b>pH:</b>	6.1 (5.0 to 7.5)
<b>Melting point/Freezing point:</b>	NA
<b>Initial Boiling Point/Boiling Point Range:</b>	NA
<b>Evaporation Rate:</b>	NA
<b>Flammability (solid, gas):</b>	NA
<b>Upper/Lower Flammability or Explosive Limits:</b>	NA
<b>Vapor Pressure:</b>	NA
<b>Vapor Density:</b>	NA
<b>Specific Gravity:</b>	NA
<b>Solubility:</b>	NA
<b>Partition coefficient: n-octanol/water:</b>	NA
<b>Auto-ignition temperature:</b>	NA
<b>Decomposition temperature:</b>	NA

**10. STABILITY AND REACTIVITY**

<b>Reactivity</b>	Not determined.
<b>Chemical Stability</b>	Stable under standard use and storage conditions.
<b>Hazardous Reactions</b>	Not determined.
<b>Conditions to avoid</b>	Not determined.
<b>Incompatibilities</b>	Not determined.
<b>Hazardous decomposition products</b>	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and oxides of sulfur.
<b>Hazardous Polymerization</b>	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:

<b>Ingredient(s)</b>	<b>Percent</b>	<b>Test Type</b>	<b>Route of Administration</b>	<b>Value</b>	<b>Units</b>	<b>Species</b>
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

<b>Aspiration Hazard</b>	None anticipated from normal handling of this product.
<b>Dermal Irritation/Corrosion</b>	None anticipated from normal handling of this product.
<b>Ocular Irritation/Corrosion</b>	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce discomfort.
<b>Dermal or Respiratory Sensitization</b>	None anticipated from normal handling of this product. In clinical use, allergic hypersensitivity reactions to heparin have occurred.
<b>Reproductive Effects</b>	In studies in animals, heparin use during gestation has not produced teratogenic effects. In animals, heparin does not cross the placenta and is not distributed into breast milk. In clinical use, heparin has not been associated with fetal malformations. However, an increase in premature deliveries (about 1 in 5 cases) and neonatal mortality (still-birth in about 1 in 8 cases) has been reported when heparin was administered during pregnancy. However, further study has suggested that these effects may have been associated with co-morbid conditions that independently affected pregnancy outcomes.
<b>Mutagenicity</b>	Studies to evaluate the genotoxic potential of heparin have not been conducted.

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**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.

**Persistence/Biodegradability** Not determined for product.

**Bioaccumulation** Not determined for product.

**Mobility in Soil** Not determined for product.

**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**

**ADR/ADG/ DOT STATUS:** Not regulated

**IMDG STATUS:** Not regulated

**ICAO/IATA STATUS:** Not regulated

**Transport Comments:** None

**15. REGULATORY INFORMATION**

**USA Regulations**

Substance	TSCA Status	CERCLA Status	SARA 302 Status	SARA 313 Status	PROP 65 Status
Heparin Sodium	Listed	Not Listed	Not Listed	Not Listed	Not Listed

**RCRA Status** Not Listed

**U.S. OSHA Classification** Target Organ Toxin  
Possible Irritant

**GHS Classification** \*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

**Hazard Class** Not Applicable

**Hazard Category** Not Applicable

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<b>Signal Word</b>	Not Applicable
<b>Symbol</b>	Not Applicable
<b>Prevention</b>	P260 - Do not breathe dust/fume/gas/mist/vapors/spray.
<b>Hazard Statement</b>	Not Applicable
<b>Response:</b>	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.

### 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

<b>Classification(s):</b>	Not Applicable
<b>Symbol:</b>	Not Applicable
<b>Indication of Danger:</b>	Not Applicable
<b>Risk Phrases:</b>	R00 - Not Applicable
<b>Safety Phrases:</b>	S23 - Do not breathe vapor. S24 - Avoid contact with 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
LD50	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: Hospira GEHS

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