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SAFETY DATA SHEET (SDS)

Revision: 001

HEPARIN I. V. FLUSH SYRINGE, USP

SECTION 1: IDENTIFICATION

Manufacturer Name and Address: Medefil, Inc.
250 Windy Point Drive
Glendale Heights, Illinois 60139
USA

Emergency Telephone Number: Tel: (630) 682 - 4600
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Product Name: **Heparin I. V. Flush Syringe, USP**

SECTION 2: HAZARD(S) IDENTIFICATION

Emergency Overview
Heparin I. V. Flush Syringe, USP, is a saline solution containing heparin sodium, a heterogeneous group of straight-chain anionic mucopolysaccharides called glycosaminoglycans, having anticoagulant properties.

U.S. OSHA GHS Classification

Physical Hazards

Hazard Class	Not Classified
Hazard Category	Not Classified

Health Hazards

Hazard Class	Not Classified
Hazard Category	Not Classified

Label Element(s)

Pictogram	NA
Signal Word	NA
Hazard Statement(s)	NA

Precautionary Statement(s)

Prevention	Do not breathe vapor or spray. Wash hands thoroughly after handling.
Response	Get medical attention if you feel unwell. 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name: Heparin Sodium, USP

Chemical Formula: Heparin is an acidic, polymeric mucopolysaccharide composed of units of glucuronic acid and sulfated glucosamine.

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

The other ingredients include water for injection (WFI), less than 1% include sodium chloride and hydrochloric acid; sodium hydroxide is used to adjust the pH.

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.

Skin Contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention.

Inhalation
Remove from source of exposure. If signs of toxicity occur, seek medical attention.

Ingestion
Remove from source of exposure. If signs of toxicity occur, seek medical attention.

5. FIRE FIGHTING MEASURES

Flammability
None anticipated for this aqueous product.

Fire and Explosion Hazard
None anticipated for this aqueous product.

Extinguishing Media
No special provisions required. As with any fire, use extinguishing media appropriate for the primary cause of the fire such as carbon dioxide, dry chemical extinguishing powder or foam.

Special Fire Fighting Procedures
No special provisions required. As with any fire, use normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal
Isolate area around the spill. Put on suitable protective clothing and/or equipment to avoid personal contact. Remove the liquid with suitable material and clean affected area with soap and water. Care should be taken to avoid environmental release.

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 package insert.

Special Precautions
No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure Limits		
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**
Heparin Sodium	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: 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.
AIHA WEEL: American Industrial Hygiene Association Workplace Environmental Exposure Level.
EEL: Employee Exposure Limit.
TWA: Time Weighted Average.

Respiratory Protection
Respiratory protection is normally not needed during intended product use. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor sufficient to control exposures to below the occupational Exposure Level (OEL).

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 the 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 liquid
Odor	NA
Odor Threshold	NA
pH	5.0 to 7.5
Melting Point/Freezing Point	NA
Initial Boiling Point/Boiling Point Range	NA
Evaporation Rate	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure and Density (Air =1)	NA
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 labeled storage conditions.
Hazardous Reactions	Not determined
Conditions to Avoid	Not determined
Incompatibilities	Not determined
Hazardous Decomposition Products	Not determined
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Not determined for the product formulation. Information for the active ingredient 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

LD50: Dosage that produces 50% mortality.

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

None anticipated from the normal handling of this product.

Dermal or Respiratory Sensitization
None anticipated from the normal handling of this product.

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.

Carcinogen Lists

IARC:	Not listed
NTP:	Not listed
OSHA:	Not listed

Specific Target Organ Toxicity (Single Exposure)
NA

Specific Target Organ Toxicity (Repeat Exposure)
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

DOT Shipping Name	Not regulated.
DOT UN Number	Not regulated.

15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of EC Regulation No. 1907/2006.

State Right To Know	Refer to the applicable state to determine applicability.
US TSCA Status	Exempt. However, heparin sodium is listed on the TSCA inventory.
Canada DSL	Heparin Sodium is listed on the DSL.
EU Classification	Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

16. OTHER INFORMATION

Refer to Medefil, Inc. prescribing information for further information at http://www.medefilinc.com

CAS:	Chemical Abstracts Service Number
DSL:	Domestic Substances List
DOT:	Department of Transportation
EU:	European Union
IARC:	International Agency for Research on Cancer
LD:	Lethal Dose
NTP:	National Toxicology Program
OSHA:	Occupational Safety and Health Agency
TSCA:	Toxic Substances Control Act

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