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
Fax: (630) 681 - 9100

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OSHA-PEL</td>
</tr>
<tr>
<td>Heparin Sodium</td>
<td>8-hr TWA: Not Established</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heparin Sodium</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>&gt;5770</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt;5000</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Heparin Sodium</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>2902</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2800</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1000</td>
<td>mg/kg</td>
<td>Dog</td>
</tr>
<tr>
<td>Heparin Sodium</td>
<td>100</td>
<td>LD50</td>
<td>Intraperitoneal</td>
<td>&gt;2500</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
</tbody>
</table>

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.

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## 12. ECOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Toxicity</td>
<td>Not determined for product.</td>
</tr>
<tr>
<td>Persistence/Biodegradability</td>
<td>Not determined for product.</td>
</tr>
<tr>
<td>Bioaccumulation</td>
<td>Not determined for product.</td>
</tr>
<tr>
<td>Mobility in Soil</td>
<td>Not determined for product.</td>
</tr>
</tbody>
</table>

## 13. DISPOSAL CONSIDERATIONS

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waste Disposal</td>
<td>All waste materials must be properly characterized. Further, disposal should</td>
</tr>
<tr>
<td></td>
<td>be performed in accordance with the federal, state or local regulatory</td>
</tr>
<tr>
<td></td>
<td>requirements.</td>
</tr>
<tr>
<td>Container Handling and Disposal</td>
<td>Dispose of container and unused contents in accordance with federal, state</td>
</tr>
<tr>
<td></td>
<td>and local regulations.</td>
</tr>
</tbody>
</table>

## 14. TRANSPORTATION INFORMATION

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOT Shipping Name</td>
<td>Not regulated.</td>
</tr>
<tr>
<td>DOT UN Number</td>
<td>Not regulated.</td>
</tr>
</tbody>
</table>

## 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
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

The above information is believed to be accurate and represents the best information currently available
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