HAEMATOLOGIC TECHNOLOGIES, INC.

Safety Data Sheet
Human Coagulation Factor IXa

SECTION 1: Identification

1.1 Product identifier

Product name: Human Coagulation Factor IXa
Product number: HCIXA-0050

1.2 Other means of identification

Human Factor IXa, plasma protein

1.4 Supplier's details

Name: Haematologic Technologies, Inc.
Address: 57 River Road
           Essex Junction, VT 05452
           USA
Telephone: +1 (802) 878-1777
Fax: +1 (802) 878-1776
email: hti@haemtech.com

1.5 Emergency phone number(s)

+1 (802) 878-1777 Hours of operation: M-F 08:00-16:30 EST
+1 (800) 424-9300 (CHEMTREC®) during non-company hours

SECTION 2: Hazard identification

General hazard statement

Product of human plasma. Handle as if capable of transmitting infectious agents. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

2.1 Classification of the substance or mixture

GHS classification in accordance with OSHA (29 CFR 1910.1200)

Not a hazardous substance or mixture.

2.2 GHS label elements, including precautionary statements

Not a hazardous substance or mixture.

2.3 Other hazards which do not result in classification

This product is formulated in 50% glycerol/water (v/v). Please also see SDS sheets for Glycerol.

SECTION 3: Composition/information on ingredients
3.2 Mixtures

### Hazardous components

<table>
<thead>
<tr>
<th>Component</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLYCEROL (CAS no.: 56-81-5; EC no.: 200-289-5)</td>
<td>50 % (Volume)</td>
</tr>
<tr>
<td>WATER (CAS no.: 7732-18-5)</td>
<td>50 % (Volume)</td>
</tr>
<tr>
<td>Human Coagulation Factor IXa</td>
<td>&gt; 0 - &lt; 1 % (Weight)</td>
</tr>
</tbody>
</table>

SECTION 4: First-aid measures

4.1 Description of necessary first-aid measures

- **General advice**: Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

- **If inhaled**: If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

- **In case of skin contact**: Rinse with plenty of water. Get medical attention if irritation develops and persists.

- **In case of eye contact**: Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

- **If swallowed**: Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms/effects, acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

4.3 Indication of immediate medical attention and special treatment needed, if necessary

No data available.

SECTION 5: Fire-fighting measures

5.1 Suitable extinguishing media

Carbon dioxide, dry chemical powder, or appropriate foam. Water spray.

5.2 Specific hazards arising from the chemical

No data available.

5.3 Special protective actions for fire-fighters

Special fire fighting precautions: wear self-contained breathing apparatus and protective clothing to prevent inhalation and contact with eyes and skin.

Further information

No data available.

SECTION 6: Accidental release measures
6.1 Personal precautions, protective equipment and emergency procedures
Chemical safety goggles, protective clothing and shoes, and protective rubber gloves.

6.2 Environmental precautions
No data available.

6.3 Methods and materials for containment and cleaning up
Blot-up liquid spills with absorbent paper. Decontaminate area by soaking with a 5% bleach solution (0.25% sodium hypochlorite), and allowing a 15 minute contact time. Dispose of all contaminated materials by autoclaving or by following your institutions guidelines for disposal of biohazard material.

Reference to other sections
For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Wear chemical resistant gloves, chemical safety goggles, and protective clothing.

Human source material from which this product was derived was found negative (or non-reactive) for anti-HIV-1/2, Syphilis (STD), anti-HCV-2.0, anti-HBcore antigen, and anti-HTLV-1/2, using approved test methods. Since no test method can offer complete assurance that infectious agents are absent, this product should be handled observing the same safety precautions employed when handling any potentially infectious materials.

7.2 Conditions for safe storage, including any incompatibilities
Store this material in a container that will contain any accidental leaks or spills. Store at the temperature indicated on the product data sheet.

Specific end use(s)
Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

CAS: 56-81-5
Glycerin (mist)
- Cal/OSHA: PNOR PEL inhalation; NIOSH: See Appendix D REL inhalation
Glycerin (mist), Respirable fraction
- Cal/OSHA: 5 mg/m3, PNOR PEL inhalation; OSHA: 5 mg/m3 PEL inhalation
Glycerin (mist), Total dust
- Cal/OSHA: 10 mg/m3 , PNOR PEL inhalation; OSHA: 15 mg/m3 PEL inhalation

8.2 Appropriate engineering controls
Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

8.3 Individual protection measures, such as personal protective equipment (PPE)

Pictograms

Eye/face protection
Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

**Skin protection**  
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove’s outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

**Body protection**  
Impervious clothing, Flame retardant antistatic protective clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

**Respiratory protection**  
Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

**Thermal hazards**  
No data available.

**Environmental exposure controls**  
No data available.

### SECTION 9: Physical and chemical properties

**Information on basic physical and chemical properties**

- **Appearance/form**: Clear liquid
- **Odor**: None
- **Odor threshold**: No data available.
- **pH**: No data available.
- **Melting point/freezing point**: No data available.
- **Initial boiling point and boiling range**: No data available.
- **Flash point**: No data available.
- **Evaporation rate**: No data available.
- **Flammability (solid, gas)**: No data available.
- **Upper/lower flammability limits**: No data available.
- **Upper/lower explosive limits**: No data available.
- **Vapor pressure**: No data available.
- **Vapor density**: No data available.
- **Relative density**: No data available.
- **Solubility(ies)**: No data available.
- **Partition coefficient: n-octanol/water**: No data available.
- **Auto-ignition temperature**: No data available.
- **Decomposition temperature**: No data available.
- **Viscosity**: No data available.
- **Explosive properties**: No data available.
- **Oxidizing properties**: No data available.

### SECTION 10: Stability and reactivity

**10.1 Reactivity**  
No data available.

**10.2 Chemical stability**
No data available.

10.3 Possibility of hazardous reactions
No data available.

10.4 Conditions to avoid
No data available.

10.5 Incompatible materials
No data available.

10.6 Hazardous decomposition products
No data available.

SECTION 11: Toxicological information

Information on toxicological effects

Acute toxicity
Glycerol:
LC50 Oral - Rat - 12,600 mg/kg
LC50 Skin - Rabbit - >10,000 mg/kg

Skin - Rabbit - 24 hours
Result: Mild skin irritation

Eyes - Rabbit - 24 hours
Result: Mild eye irritation

Skin corrosion/irritation
No data available.

Serious eye damage/irritation
No data available.

Respiratory or skin sensitization
No data available.

Germ cell mutagenicity
No data available.

Carcinogenicity
No data available.

Reproductive toxicity
No data available.

Summary of evaluation of the CMR properties
No data available.

STOT-single exposure
No data available.

STOT-repeated exposure
No data available.
Aspiration hazard
No data available.

Additional information
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated; however:

May be harmful by inhalation, ingestion, or skin absorption. May cause irritation. Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.

Human source material. The toxicological properties have not been thoroughly investigated.

SECTION 12: Ecological information

Toxicity
GLYCEROL
LC50 Skin - Oncorhynchus mykiss (rainbow trout) - 51,000 mg/l - 96 hours

Persistence and degradability
No data available.

Bioaccumulative potential
No data available.

Mobility in soil
No data available.

Results of PBT and vPvB assessment
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

Other adverse effects
No data available.

SECTION 13: Disposal considerations

Disposal of the product
Disposal should be done in accordance with the existing disposal practices employed for infectious waste at your institution.

Disposal of contaminated packaging
Soak with a 5% bleach solution (0.25% sodium hypochlorite), and allowing a 15 minute contact time. Dispose of all contaminated materials by autoclaving or by following your institutions guidelines for disposal of biohazard material.

SECTION 14: Transport information

DOT (US)
Not dangerous goods

IMDG
Not dangerous goods

IATA
Not dangerous goods

SECTION 15: Regulatory information
15.1 Safety, health and environmental regulations specific for the product in question

SARA 302 Components
None present or none present in regulated quantities.

SARA 311/312 Hazards
Chronic Health Hazard

SARA 313 Components
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

California Prop. 65 Components
No ingredient regulated by CA Prop 65 present.

New Jersey Right To Know Components
Common name: GLYCERIN
CAS number: 56-81-5

Massachusetts Right To Know Components
Chemical name: GLYCERIN
CAS number: 56-81-5

Pennsylvania Right To Know Components
Chemical name: GLYCERIN
CAS number: 56-81-5

SECTION 16: Other information

16.1 Further information/disclaimer
DISCLAIMER: The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigation to determine the suitability of information for their particular purposes. In no event shall Haematologic Technologies, Inc. be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, whatsoever arising, even if Haematologic Technologies, Inc. has been advised of the possibility of such damages.