

**Safety Data Sheet
Human Coagulation Factor IX**

SECTION 1: Identification

1.1 Product identifier

Product name Human Coagulation Factor IX
Product number HCIX-0040

1.2 Other means of identification

Blood Coagulation factor IX

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

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3.2 Mixtures

Hazardous components

Component	Concentration
GLYCEROL (CAS no.: 56-81-5; EC no.: 200-289-5) CLASSIFICATIONS: No data available. HAZARDS: No data available.	50 % (Volume)
WATER (CAS no.: 7732-18-5) Human Coagulation Factor IX (CAS no.: 9001-28-9) CLASSIFICATIONS: No data available. HAZARDS: No data available.	50 % (Volume) > 0 - < 1 % (Weight)

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

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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

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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

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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

Glycercol:

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.

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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

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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

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