

HAEMATOLOGIC TECHNOLOGIES, INC.

Safety Data Sheet Human Factor Xa - gla domainless SECTION 1: Identification

1.1 Product identifier

Product name Human Factor Xa - gla domainless

HCXA-GD

Product number

1.3 Recommended use of the chemical and restrictions on use Laboratory research use only.

1.4 Supplier's details

Name Address	Haematologic Technologies, Inc. 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 Hepes buffered saline. Please see SDS sheets for Hepes (CAS 7365-45-9) and Sodium Chloride (CAS 7647-14-5)

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Hazardous components

Component	Concentration
Human Factor Xa-GD	> 0 - < 1 % (Weight)
CLASSIFICATIONS: No data available. HAZARDS: No data available.	
HEPES (CAS no.: 7365-45-9; EC no.: 230-907-9)	0.4 % (Weight)
CLASSIFICATIONS: Eye damage/irritation (chapter 3.3), Cat. 2A; Skin corrosion/irritation (chapter 3.2) toxicity, single exposure (chapter 3.8), Cat. 3. HAZARDS: No data available.	, Cat. 2; Specific target organ
Sodium Chloride (CAS no.: 7647-14-5; EC no.: 231-598-3)	0.9 % (Weight)
CLASSIFICATIONS: Eye damage/irritation (chapter 3.3), Cat. 2A. HAZARDS: No data available.	
WATER (CAS no.: 7732-18-5)	98.7 % (Volume)

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 attendence. 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

8.2 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)





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

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 Sodium Chloride LD50 Oral - Rat - 4,000 mg/kg

LD50 Skin - Rabbit - 10,000 mg/kg

LC50 Inhalation - Rat - 42 mg/l - 1 hour

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

Sodium Chloride EC50 - Daphnia magna (water flea) - 340.7 mg/l - 48 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

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302

SARA 311/312 Hazards

HEPES; Threshold Planning Quantity: 500lbs

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

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

New Jersey Right To Know Components

Sodium Chloride; CAS 7647-14-15

Massachusetts Right To Know Components

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components

Sodium Chloride; CAS 7647-14-15

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.