

in accordance with Regulation (EC) No. 1907/2006 as amended

Human Factor Xa

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier Product name: Human Factor Xa Catalog number: HFXA

1.2. Relevant identified uses of the substance or mixture and uses advised against Identified uses: Laboratory chemicals, for research use only Uses advised against: Not for clinical or diagnostic use

1.3. Details of the supplier of the safety data sheet

Molecular Innovations, Inc. 46430 Peary Court, Novi, MI 48377, USA Tel: 248-896-0142 Fax: 248-896-0148

1.4. Emergency telephone number

Emergency number: 248-896-0142

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture Not a hazardous substance or mixture.

2.2. GHS label elements, including precautionary statements Not a hazardous substance or mixture. No labeling applicable.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS None.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

| Name | CAS No. | EC No. | Concentration | Classification |
|-----------------------|-----------|-----------|---------------|----------------|
| Coagulation Factor Xa | 9002-05-5 | 232-649-2 | <1% | Not classified |
| Glycerol | 56-81-5 | 200-289-5 | 50% | Not classified |

No ingredients are hazardous according to OSHA criteria. No components need to be disclosed according to the applicable regulations.

SECTION 4: First aid measures

4.1. Description of first aid measures

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration.

In case of skin contact

Wash off with soap and plenty of water.

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water.

4.2. Most important symptoms and effects, both acute and delayed

None known.



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4.3. Indication of any immediate medical attention and special treatment needed

In all cases of doubt, or when symptoms persist, seek medical attention.

SECTION 5: Firefighting measures

5.1. Extinguishing media Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Carbon oxides.

5.3. Advice for firefighters

Use normal individual fire protective equipment. Wear self contained breathing apparatus for fire fighting if necessary.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures Avoid all unnecessary exposure. Avoid breathing vapors, mist or gas. For personal protection see section 8.

6.2. Environmental precautions

No additional information available.

6.3. Methods and material for containment and cleaning up

Take up liquid spill into inert absorbent material. Clean thoroughly.

6.4. Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling For precautions see section 2.2.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place.

7.3. 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

Components with workplace control parameters

| Name | CAS No. | Value | Control Parameters | Basis |
|----------|---------|-------|---------------------------|--|
| Glycerol | 56-81-5 | TWA | 10.0 mg/m3 | USA. ACGIH Threshold Limit Values (TLV) |
| | | TWA | 15.0 mg/m3 | USA. Occupational Exposure Limits (OSHA) - |
| | | | | Table Z-1 Limits for Air Contaminants |
| | | TWA | 5.0 mg/m3 | USA. Occupational Exposure Limits (OSHA) - |
| | | | | Table Z-1 Limits for Air Contaminants |

8.2. Exposure controls

Appropriate engineering controls

General industrial hygiene practice.

Personal protective equipment

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

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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. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection: Not required. For nuisance exposures use type OV/AG (US) or type ABEK (EU EN 14387) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). Control of environmental exposure: Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties Physical state: Liquid Color: No data available Odor: No data available Odor threshold: No data available pH: No data available Melting point: No data available Freezing point: No data available Boiling point: No data available Flash point: No data available Evaporation rate: No data available Decomposition temperature: No data available Flammability (solid, gas): No data available Vapor pressure: No data available Relative vapor density: No data available Relative density: No data available Solubility: Water soluble Viscosity: No data available Explosive properties: No data available Oxidizing properties: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity Stable under recommended storage conditions.

10.2. Chemical stability Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions No data available.

10.4. Conditions to avoid No data available.

10.5. Incompatible materials Strong oxidizing agents.

10.6. Hazardous decomposition products No data available.

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

LD50 Oral (rat): 12,600 mg/kg LD50 Dermal (rabbit): >10,000 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/eye irritation Causes eye irritation.

Respiratory or skin sensitization No data available.

Germ cell mutagenicity

No data available.

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

No data available.

Specific target organ toxicity-single exposure

No data available.

Specific target organ toxicity repeated exposure

No data available.

Aspiration hazard

No data available.

Additional information

RTECS: MA8050000

Prolonged or repeated exposure may cause nausea, headache, vomiting. To the best of our knowledge the product does not present any particular risk under normal conditions of use. The chemical, physical, and toxicological properties have not been thoroughly investigated.

Kidney - Irregularities - Based on Human Evidence

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SECTION 12: Ecological information

12.1. Toxicity Presents no specific risk for the environment in small amounts.

12.2 Persistence and degradability

No data available.



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12.3 Bioaccumulative potential No data available.

12.4 Mobility in soil No data available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects

No data available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging

Dispose of as unused product.

SECTION 14: Transport information

Not dangerous goods in accordance with DOT (US) / ADR / RID / ADNR / IMDG / ICAO / IATA 14.1 UN number Not regulated.

14.2 UN proper shipping name Not regulated.

14.3 Transport hazard class(es) Not regulated.

14.4 Packaging group Not regulated.

14.5 Environmental hazards No data available.

14.6 Special precautions for user

No data available.

14.7 Transport in bulk according to Annex II of Marpol73/78 and the IBC Code No data available.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

United States Restrictions

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

SARA 311/312 Hazards: No SARA Hazards.

Massachusetts Right To Know Components: Glycerol, CAS No. 56-81-5.

Pennsylvania Right To Know Components: Glycerol, CAS No. 56-81-5.

New Jersey Right To Know Components: Glycerol, CAS No. 56-81-5.

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.



European Union Restrictions

Act No. 350/2011 Coll., to regulate chemical substances and chemical mixtures and to amend some statutes, as amended. Implemented regulations to Act No. 350/2011 Coll., as amended The Waste Act as amended. Government Decree No. 361/2007 Coll., to regulate the conditions of occupational health and safety, as amended. Regulation of the European Parliament and the Council (EC) No. 1907/2006 (REACH). Regulation of the European Parliament and the Council (EC) No. 1272/2008 (CLP). Commission Regulation (EU) No. 453/2010. Directives 67/548/EEC as amended and 1999/45/EC as amended.

15.2. Chemical safety assessment

Chemical safety assessment has not been carried out.

SECTION 16: Other information

Hazardous Material Information System (HMIS) Rating Health Hazard: 0 Chronic Health Hazard: Flammability: 0 Physical Hazard: 0

National Fire Protection Association (NFPA) Rating Health Hazard: 0

Fire Hazard: 0 Reactivity Hazard: 0

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