

according to Regulation (EC) No. 1907/2006 as amended by (EU) No. 2020/878

Section 1. Identification of the Substance/Mixture and of the Company/Undertaking

- 1.1 Product Code:** HFXIII 1313
Product Name: Human Factor XIII
Synonyms: Fibrin Stabilizing Factor
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant identified uses: For research use only.
- 1.3 Details of the Supplier of the Safety Data Sheet:**
Company Name: Enzyme Research Laboratories
1801 Commerce Dr.
South Bend, IN 46628
Web site address: www.enzymeresearch.com
- 1.4 Emergency telephone number:**
Emergency Contact: Within USA and Canada: +1 (800) 729-5270
Outside USA and Canada: +1 (574) 288-2268

Section 2. Hazards Identification

- 2.1 Classification of the Substance or Mixture:**
2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP]:
Eye Irritation, Category 2
Skin Sensitization, Category 1
Respiratory Sensitization, Category 1
- 2.2 Label Elements:**
2.2.1 Labeling according to Regulation (EC) No 1272/2008 [CLP]:



GHS Signal Word: Warning

GHS Hazard Phrases:

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

GHS Precaution Phrases:

P261: Avoid breathing {dust/fume/gas/mist/vapors/spray}.

P264: Wash thoroughly after handling

P272: Contaminated work clothing should not be allowed out of the workplace

P280: Wear protective gloves/protective clothing/eye protection/face protection

P284: In case of inadequate ventilation wear respiratory protection.

GHS Response Phrases:

P302+352: IF ON SKIN: Wash with plenty of water>

P304+340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P333+313: If skin irritation or rash occurs, get medical advice/attention.

P337+313: If eye irritation persists: Get medical advice/attention

P342+311: If experiencing respiratory symptoms call a POISON CENTER or doctor/physician.

P362+364: Take off contaminated clothing and wash it before reuse.

GHS Storage and Disposal Phrases:

Please refer to Section 7 for Storage and Section 13 for Disposal information

2.3 Adverse Human Health Biohazard - Handle as if capable of transmitting infectious agents.

Effects and Symptoms: Causes mild skin irritation.
Material may be irritating to the mucous membranes and upper respiratory tract.
May be harmful by inhalation, ingestion, or skin absorption.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause eye or respiratory system irritation.
None of the components are known to possess endocrine disrupting properties per the criteria set out in Delegated Regulation (EU) 2017/2100 or Regulation (EU) 2018/605.

To the best of our knowledge, the toxicological properties have not been thoroughly investigated

Section 3. Composition/Information on Ingredients

CAS # / RTECS #	Hazardous Components (Chemical Name)/ REACH Registration No.	Concentration	EC No./ EC Index No.	GHS Classification
9013-56-3 NA	Human Factor XIII	~75 – 78%	NA NA	No data available.
7647-14-5 VZ4725000	Sodium chloride	~0.5 – 1%	231-598-3 NA	No data available.
77-86-1 TY2900000	Tris 01-2119957659-16	~0.5 – 1%	201-064-4 NA	No data available.
60-00-4 AH4025000	Edetic acid	~0.5 – 1%	200-449-4 607-429-00-8	Eye Irrit. 2; H319
9087-70-1 YN5080000	Aprotinin	~0.5 – 1%	232-994-9 NA	Skin Sens. 1; H317 Resp. Sens. 1; H334
56-81-5 MA8050000	Glycerol 01-2119471987-18	~20%	200-289-5 NA	No data available.

Section 4. First Aid Measures

- 4.1 Description of First Aid** No data available.
- Measures:**
- In Case of Inhalation:** Move person to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel.
Get immediate medical attention.
- In Case of Skin Contact:** Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.
- In Case of Eye Contact:** Flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.
- In Case of Ingestion:** Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

Section 5. Fire Fighting Measures

- 5.1 Suitable Extinguishing** Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray.
- Media:** Use water spray to cool fire-exposed containers.
- Unsuitable Extinguishing** A solid water stream may be inefficient.
- Media:**
- 5.2 Flammable Properties and** No data available.
- Hazards:**
- Flash Pt:** No data.
- Explosive Limits:** LEL: No data. UEL: No data.
- Autoignition Pt:** No data.
- 5.3 Fire Fighting Instructions:** As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

Section 6. Accidental Release Measures

- 6.1 Protective Precautions,** Avoid raising and breathing dust, and provide adequate ventilation.
Protective Equipment and As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator,
Emergency Procedures: and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).
- 6.2 Environmental** Take steps to avoid release into the environment, if safe to do so.
Precautions:
- 6.3 Methods and Material For** Contain spill and collect, as appropriate.
Containment and Cleaning Transfer to a chemical waste container for disposal in accordance with local regulations.
Up: After removal, flush contaminated area and all cleaning materials with a 10% bleach aqueous solution.

Section 7. Handling and Storage

- 7.1 Precautions To Be Taken** Avoid breathing dust/fume/gas/mist/vapours/spray.
in Handling: Avoid prolonged or repeated exposure.
- 7.2 Precautions To Be Taken** Keep container tightly closed.
in Storing: Store in accordance with information listed on the product insert.

Section 8. Exposure Controls/Personal Protection

8.1 Exposure Parameters:

CAS #	Partial Chemical Name	Britain EH40	France VL	Europe
9013-56-3	Human Factor XIII	No data.	No data.	No data.
7647-14-5	Sodium Chloride	No data.	No data.	No data.
77-86-1	Tris	TWA: 5.0 mg/m3	TWA: 5 mg/m3	No data.
60-00-4	Edetic acid	No data.	No data.	No data.
9087-70-1	Aprotinin	No data.	No data.	No data.
56-81-5	Glycerol	TWA: 10 mg/m3 () STEL: ()	TWA: 10 mg/m3	No data.

CAS #	Partial Chemical Name	OSHA TWA	ACGIH TWA	Other Limits
9013-56-3	Human Factor XIII	No data.	No data.	No data.
7647-14-5	Sodium Chloride	No data.	No data.	No data.
77-86-1	Tris	TWA: 5 mg/m3	CEIL: 5 mg/m3 (salts)	No data.
60-00-4	Edetic acid	No data.	No data.	No data.
9087-70-1	Aprotinin	No data.	No data.	No data.
56-81-5	Glycerol	PEL: 15 (dust); 5 (resp.) mg/m3	TLV: 10 mg/m3	No data.

8.2 Exposure Controls:

- 8.2.1 Engineering Controls** Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.
(Ventilation etc.):
- 8.2.2 Personal protection equipment:**
- Eye Protection:** Safety glasses
- Protective Gloves:** Compatible chemical-resistant gloves
- Other Protective Clothing:** Lab coat
- Respiratory Equipment** NIOSH approved respirator, as conditions warrant.
(Specify Type):
- Work/Hygienic/Maintenan** Do not take internally.
ce Practices: Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower.
Wash thoroughly after handling.
No data available.

Section 9. Physical and Chemical Properties

9.1 Information on Basic Physical and Chemical Properties

Physical States: ☐ Gas ☒ Liquid (frozen) ☐ Solid (Lyophilized)

Appearance and Odor: Solid

Melting Point: No data.

Boiling Point: No data.

Flash Pt: No data.

Evaporation Rate: No data.

Explosive Limits: LEL: No data. UEL: No data.

Vapor Pressure (vs. Air or mm Hg): No data.

Vapor Density (vs. Air = 1): No data.

Specific Gravity (Water = 1): No data.

Solubility in Water: No data.

Autoignition Pt: No data.

9.2 Other Information

Percent Volatile: No data.

Section 10. Stability and Reactivity

10.1 Reactivity: No data available.

10.2 Stability: Unstable ☐ Stable ☒

10.3 Stability Note(s): Stable if stored in accordance with information listed on the product insert.

Polymerization: Will occur ☐ Will not occur ☒

10.4 Conditions To Avoid: No data available.

10.5 Incompatibility - Materials To Avoid: No data available.

10.6 Hazardous Decomposition Or Byproducts: No data available.

Section 11. Toxicological Information

11.1 Information on Toxicological Effects: The toxicological effects of this product have not been thoroughly studied.

CAS #	Hazardous Components (Chemical Name)	NTP	IARC	ACGIH	OSHA
9013-56-3	Human Factor XIII	n.a.	n.a.	n.a.	n.a.
7647-14-5	Sodium Chloride	n.a.	n.a.	n.a.	n.a.
77-86-1	Tris	n.a.	n.a.	n.a.	n.a.
60-00-4	Edetic acid	n.a.	n.a.	n.a.	n.a.
9087-70-1	Aprotinin	n.a.	n.a.	n.a.	n.a.
56-81-5	Glycerol	n.a.	n.a.	n.a.	n.a.

Section 12. Ecological Information

12.1	Toxicity:	Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.
12.2	Persistence and Degradability:	No data available.
12.3	Bioaccumulative Potential:	No data available.
12.4	Mobility in Soil:	No data available.
12.5	Results of PBT and vPvB assessment:	No data available.
12.6	Endocrine disrupting properties:	No components with endocrine disrupting properties
12.7	Other adverse effects:	No data available

Section 13. Disposal Considerations

13.1 Waste Disposal Method: Dispose in accordance with local, state, and federal regulations.

Section 14. Transport Information

14.1 LAND TRANSPORT (US DOT):

DOT Proper Shipping Name: Not dangerous goods.

DOT Hazard Class:

UN/NA Number:

14.1 LAND TRANSPORT (European ADR/RID):

ADR/RID Shipping Name: Not dangerous goods.

UN Number:

Hazard Class:

14.3 AIR TRANSPORT (ICAO/IATA):

ICAO/IATA Shipping Name: Not dangerous goods.

Additional Transport Information: Transport in accordance with local, state, and federal regulations.

Section 15. Regulatory Information

EPA SARA (Superfund Amendments and Reauthorization Act of 1986) Lists

CAS #	Hazardous Components (Chemical Name)	S. 302 (EHS)	S. 304 RQ	S. 313 (TRI)
9013-56-3	Human Factor XIII	No	No	No
7647-14-5	Sodium Chloride	No	No	No
77-86-1	Tris	No	No	Yes-Cat. N106
60-00-4	Edetic acid	No	Yes 5000 LB	No
9087-70-1	Aprotinin	No	No	No
56-81-5	Glycerol	No	No	No

CAS #	Hazardous Components (Chemical Name)	Other US EPA or State Lists
9013-56-3	Human Factor XIII	CAA HAP,ODC: No; CWA NPDES: No; TSCA: Yes - Inventory; CA PROP.65: No
7647-14-5	Sodium chloride	CAA HAP,ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No
77-86-1	Tris	CAA HAP,ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No
60-00-4	Edetic acid	CAA HAP,ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No
9087-70-1	Aprotinin	CAA HAP,ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No
56-81-5	Glycerol	CAA HAP,ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No

Regulatory Information Statement: This SDS was prepared in accordance with 29 CFR 1910.1200 and Regulation (EC) No.1272/2008.

Section 16. Other Information

Additional Information About No data available.

This Product:

Company Policy or Disclaimer: DISCLAIMER: This information 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 investigations to determine the suitability of the information for their particular purposes.