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: F2

Product Name: Prothrombin Fragment 2

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]:

Specific Target Organ Toxicity (Single Exposure), Category 3

Eye Irritant, Category 2

Skin Irritant, Category 2

2.2 Label Elements:

2.2.1 Labeling according to Regulation (EC) No 1272/2008 [CLP]:

GHS Signal Word: **Warning**

GHS Hazard Phrases:

H315: Causes skin irritation.
H319: Causes serious skin irritation.
H335: May cause respiratory irritation.

GHS Precaution Phrases:

P261: Avoid breathing {dust/fume/gas/mist/vapors/spray}.
P264: Wash hands thoroughly after handling
P280: Wear protective gloves/protective clothing/eye protection/face protection.

GHS Response Phrases:

P302+352: IF ON SKIN: Wash with plenty of water
P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
P304+340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P332+313: If skin irritation occurs, get medical advice/attention.
P337+313: If eye irritation occurs, get medical advice/attention.
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

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2.3 Adverse Human Health Effects and Symptoms: Biohazard - Handle as if capable of transmitting infectious agents.

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 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
78768-79-3 NA	Prothrombin Fragment 2	~98 - 99%	NA NA	No data available.
7647-14-5 VZ4725000	Sodium chloride	~0 - 2%	231-598-3 NA	No data available.
77-86-1 TY2900000	Tris 01-2119957659-16	~0 - 2%	201-064-4 NA	No data available.
206752-36-5 NA	Benzamidine	~0 - 2%	606-598-5 NA	Skin Irrit. 2; H315 Eye Irrit. 2; H319 STOT SE 3; H335
60-00-4 AH4025000	Edetic acid	~0 - 2%	200-449-4 607-429-00-8	Eye Irrit. 2; H319

Section 4. First Aid Measures

4.1 Description of First Aid Measures: No data available.

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 Media: Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray.
Use water spray to cool fire-exposed containers.

Unsuitable Extinguishing Media: A solid water stream may be inefficient.

5.2 Flammable Properties and Hazards: No data available.

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 approvedor equivalent), and full protective gear to prevent contact with skin and eyes.

Section 6. Accidental Release Measures

6.1 Protective Precautions, Protective Equipment and Emergency Procedures: Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

6.2 Environmental Precautions: Take steps to avoid release into the environment, if safe to do so.

6.3 Methods and Material For Containment and Cleaning Up: Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations. 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 in Handling: Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure.

7.2 Precautions To Be Taken in Storing: Keep container tightly closed. 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
78768-79-3	Prothrombin Fragment 2	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.
206752-36-5	Benzamidine	No data.	No data.	No data.
60-00-4	Edetic acid	No data.	No data.	No data.

CAS #	Partial Chemical Name	OSHA TWA	ACGIH TWA	Other Limits
78768-79-3	Prothrombin Fragment 2	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.
206752-36-5	Benzamidine	No data.	No data.	No data.
60-00-4	Edetic acid	No data.	No data.	No data.

8.2 Exposure Controls:

8.2.1 Engineering Controls (Ventilation etc.): Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

8.2.2 Personal protection equipment:

Eye Protection: Safety glasses

Protective Gloves: Compatible chemical-resistant gloves

Other Protective Clothing: Lab coat

Respiratory Equipment (Specify Type): NIOSH approved respirator, as conditions warrant.

Work/Hygienic/Maintenance Practices: Do not take internally. 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 [X] Liquid (frozen) [X] 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 [X]
10.3	**Stability Note(s):**	Stable if stored in accordance with information listed on the product insert.
	Polymerization:	Will occur [ ] Will not occur [X]
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
78768-79-3	Prothrombin Fragment 2	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.
206752-36-5	Benzamidine	n.a.	n.a.	n.a.	n.a.
60-00-4	Edetic acid	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)
78768-79-3	Prothrombin Fragment 2	No	No	No
7647-14-5	Sodium Chloride	No	No	No
77-86-1	Tris	No	No	Yes-Cat. N106
206752-36-5	Benzamidine	No	No	No
60-00-4	Edetic acid	No	No	No

CAS #	Hazardous Components (Chemical Name)	Other US EPA or State Lists
78768-79-3	Prothrombin Fragment 2	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
206752-36-5	Benzamidine	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

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 This Product: No data available.

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.