



## 2 COMPOSITION - Information on ingredients

INGREDIENT NAME (ctd.)	CONCENTRATION PERCENT BY WEIGHT
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<p><b>Tris-hydroxymethyl-aminomethane hydrochloride</b>            CAS No.: 1185-53-1            EINECS No. : 214-684-5            Hazard Classification: Xi (as raw material)            Risk Code: R36-37-38            R36: irritating to eyes            R37: irritating to respiratory system            R38: irritating to skin            Safety Code: S 26 -36</p>	<p>3.46</p>
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<p><b>Bovine Factor Xa (Lyophilized)</b></p>	<p>71 nkat</p>
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**-Antithrombin:**

Assy hazard classification:  
(24/25-29-36)

<p><b>Human Antithrombin (Lyophilized)</b></p>	<p>10 IU</p>
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**-Buffer:**

Assy hazard classification:  
(24/25-29-36)

<p><b>EDTA Disodium salt x 2H<sub>2</sub>O</b>            CAS No.: 6381-92-6            EINECS No.: 205-358-3            Hazard Classification: Xn (as raw material)            Risk Code: R22-36/37/38            R22: Harmful if swallowed            R36/37/38: Irritating to eyes, respiratory system and skin.            Safety Code: S 26-36</p>	<p>2.56</p>
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<p><b>Tris-hydroxymethyl-aminomethane</b>            CAS No.: 77-86-1            EINECS No. : 201-064-4            Hazard Classification: Xi (as raw material)            Risk Code: R36-37-38            R36: irritating to eyes            R37: irritating to respiratory system            R38: irritating to skin            Safety Code: S 26 -36</p>	<p>4.23</p>
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<p><b>Tris-hydroxymethyl-aminomethane hydrochloride</b>            CAS No.: 1185-53-1            EINECS No. : 214-684-5            Hazard Classification: Xi (as raw material)            Risk Code: R36-37-38            R36: irritating to eyes            R37: irritating to respiratory system            R38: irritating to skin            Safety Code: S 26 -36</p>	<p>1.69</p>
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## 2 COMPOSITION - Information on ingredients

INGREDIENT NAME (ctd.)	CONCENTRATION PERCENT BY WEIGHT
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**-Normal Plasma:**

**Assy hazard classification:**  
**(24/25-29-36)**

**Treated Human Plasma (Lyophilized)**

## 3. HAZARD IDENTIFICATION

### POTENTIAL HEALTH EFFECTS

#### EYES

**Substrate S-2222 / Factor Xa / Antithrombin / Buffer / Normal Plasma:** may cause irritation

#### SKIN

**Substrate S-2222:** may be absorbed through the skin with possible systemic effects.

**Factor Xa / Antithrombin / Buffer / Normal Plasma:** may cause irritation.

#### INGESTION

**Substrate S-2222:** may be harmful if swallowed. May cause blood damage with blueness of the lips (cyanosis), strong headache.

**Factor Xa / Antithrombin / Buffer / Normal Plasma:** may be harmful if swallowed.

#### INHALATION

**Substrate S-2222:** may cause blood damage with blueness of the lips (cyanosis), strong headache, nausea, coughing.

**Factor Xa / Buffer:** may cause irritation to the mucous membranes and upper respiratory tract.

**Antithrombin / Normal Plasma:** none known

## 4. FIRST AID MEASURES

#### EYES

**Substrate S-2222 / Factor Xa / Antithrombin / Buffer / Normal Plasma:**

in case of eye contact, flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.

#### SKIN

**Substrate S-2222 / Factor Xa / Antithrombin / Buffer / Normal Plasma:**

wash well with soap and water. Remove contaminated clothing and launder before use. If irritation persists, get medical attention.

#### INGESTION

**Substrate S-2222 / Factor Xa / Antithrombin / Buffer / Normal Plasma:**

flush mouth with water, without swallowing .Get medical attention or contact the local Poison Control Center.

#### INHALATION

**Substrate S-2222 / Factor Xa / Buffer:**

remove the individual to fresh air. If breathing is difficult give oxygen, get medical attention.

**Antithrombin / Normal Plasma:** none normally required.

## 5. FIRE FIGHTING MEASURES

### FLAMMABLE PROPERTIES

#### FLASH POINT

LOWER EXPLOSIVE LIMIT (%): N/A

UPPER EXPLOSIVE LIMIT (%): N/A

## FIRE AND EXPLOSION HAZARDS:

None known.

## EXTINGUISHING MEDIA

Use any extinguishing agent which is suitable for the surrounding fire.

## FIRE FIGHTING INSTRUCTIONS

Wear self-contained breathing apparatus and protective clothing that is appropriate for fighting a typical fire involving chemical materials.

## **6. ACCIDENTAL RELEASE MEASURES .**

Contain spill by placing a suitable absorbent material around the edges of the spill and work inward. Carefully scoop up into appropriate waste container for disposal.

## **7. HANDLING AND STORAGE**

### HANDLING AND STORAGE PRECAUTIONS

The sealed reagents are stable until the expiration dates shown on the labels when stored at 2-8 °C.

### Antithrombin / Normal Plasma

CAUTION: All blood products should be treated as potentially infectious.

Source material from which this product was derived was found negative when tested in accordance with FDA required tests.

No known test method can offer assurance that products derived from human blood will not transmit infectious agents.

Handle as if capable of transmitting infectious agents.

### WORK/HYGIENIC PRACTICES

Wash hands with soap and water after use.

## **8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### Engineering Controls

None normally required.

### Eye/Face protection

Safety glasses or splash goggles are recommended.

### Skin Protection

Wear rubber or plastic gloves and other protective clothing (lab coat) as required to prevent skin contact.

### Respiratory Protection

None normally required with adequate ventilation.

### Other/General Protection

None normally required.

## **9. PHYSICAL AND CHEMICAL PROPERTIES**

	<u>Substrate S-2222</u>	<u>Factor Xa</u>	<u>Antithrombin</u>	<u>Buffer</u>	<u>Normal Plasma</u>
Appearance:	lyophilized powder	lyophilized powder	lyophilized powder	liquid	lyophilized powder
Colour:	white	white	white	colourless	white-yellowish
Odour:	odourless	odourless	odourless	odourless	odourless
Density:	N/A	N/A	N/A	not available	N/A
pH:	not available	7.2-7.4 at 20-25°C	6.9-7.1 at 20-25°C	8.3-8.5 at 20-25°C	7.5 at 25°C

### BASIC PHYSICAL PROPERTIES

VAPOUR PRESSURE: not determined

SPECIFIC GRAVITY: not determined

SOLUBILITY (H<sub>2</sub>O): not determined

## 10. STABILITY AND REACTIVITY

STABILITY: stable

### CONDITIONS TO ALLOW (STABILITY)

See Insert Sheet.

### INCOMPATIBLE MATERIALS

- pNA: strong oxidizing agents, strong acids and bases.
- Tris-hydroxymethyl-aminomethane: copper, brass, aluminum and oxidizing materials.
- EDTA: strong oxidizing materials.

### HAZARDOUS DECOMPOSITION PRODUCTS

- Substrate S-2222 / Factor Xa / Buffer: harmful fumes of oxides of carbon and nitrogen may be formed during thermal decomposition.
- Antithrombin / Normal Plasma: none known.

HAZARDOUS POLYMERIZATION: will not occur

## 11. TOXICOLOGICAL INFORMATION

### MISCELLANEOUS TOXICOLOGICAL INFORMATION

-Tris-hydroxymethyl-aminomethane: orl-rat LD50 5900 mg/kg . No toxic effected noted. (NIOSH).

-pNA: orl-rat LD50 750 mg/Kg; TLV-TWA 3.0 mg/m3; mutagenic data (NIOSH).

Peptide: ivn-mouse LD50 appr. 100mg/kg.

pNA is chemically coupled to the peptide molecule but is cleaved by proteolytic enzyme e.g. trypsin in digestive tract.

-EDTA Na<sub>2</sub> x 2H<sub>2</sub>O: orl-rat LD50 2000 mg/Kg; orl-rbt LD50 2300 mg/Kg; experimental mutagenic and teratogenic data (NIOSH).

The health effects noted above are based on the extrapolation of data on the pure product ingredients. To the best of our knowledge, no health effects have been identified for the product mixture under normal conditions of use, although the health effects of the product have not been thoroughly investigated.

## 12. ECOLOGICAL INFORMATION

### OTHER ENVIRONMENTAL INFORMATION

pNA: Daphnia Magna : 48 Hr-LC50 = 20-30 ppm, slightly toxic.

Use in accordance with good laboratory practice. Do not waste in the environment.

## 13. DISPOSAL CONSIDERATIONS

Based on EEC Directive No. 75/442 and 78/319 and following modifications, the product waste is classified as toxic and harmful (pNA).

Dispose of in accordance with local regulations.

Used waste products, surplus products or spillage products shall be disposed of in accordance with national and local laws. It is up to the user to classify the waste correctly prior to disposal.

## 14. TRANSPORT INFORMATION

None.

## 15. REGULATORY INFORMATION

This product is classified and labelled in accordance with EEC Directive 88/379 and EEC Directive 91/155 and following modifications. The health hazard classification has been determined based on composition and hazard data of each ingredient.

Physical and health hazard information on the reagent mixture has not been determined.

Any physical and health hazard information noted is based on a) evaluation of data of the pure ingredient and b) concentration of each ingredient.

### Kit Hazard Classification

- EEC Symbol: N/A
- Risk Code: N/A.
- Safety Code: **S24/25 - 29 - 36**
  - S24/25:** avoid contact with skin and eyes.
  - S29:** do not empty into drains.
  - S36:** wear suitable protective clothing.

## 16. OTHER INFORMATION

### REFERENCE DOCUMENTATION

Primary references used in the preparation of this document:

1. Product Specification.
2. Product Insert.

### NOTE

The information supplied in this Safety Data Sheet represents the data and best information available at the date of preparation. It is provided with the aim of allowing proper and safe use, storage, transport and disposal of the product. It is not to be considered as a warranty or specification of product quality. It is related to the materials specifically indicated and does not apply if these are used in combination with other materials or during processes not specifically indicated in the text of this Safety Data Sheet.

Rev.	Date	Drawn by
0	September 2000	A. Lavezzari 