

2 COMPOSITION - Information on ingredients

INGREDIENT NAME (ctd.)	CONCENTRATION PERCENT BY WEIGHT
------------------------	------------------------------------

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

Tris-hydroxymethyl-aminomethane 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	0.42
---	------

Tris-hydroxymethyl-aminomethane hydrochloride 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	0.32
---	------

Heparin Sodium USP from porcine	3 IU/mL
--	---------

Bovine Factor Xa	90 nkat/vial
-------------------------	--------------

Bovine Albumin	0.16
-----------------------	------

3. HAZARD IDENTIFICATION

POTENTIAL HEALTH EFFECTS

EYES

Substrate Solution S-2772: may cause irritation.

Factor Xa Solution: avoid contact, may cause irritation

SKIN

Substrate Solution S-2772: may be absorbed through the skin with possible systemic effects.

Factor Xa Solution: avoid contact, may cause irritation.

INGESTION

Substrate Solution S-2772: may be harmful if swallowed. may cause blood damage with blueness of the lips (cyanosis), strong headache.

Factor Xa Solution: may be harmful if swallowed.

INHALATION

Substrate Solution S-2772: may cause blood damage with blueness of the lips (cyanosis), strong headache, nausea, coughing.

Factor Xa Solution: may cause irritation to the mucous membranes and upper respiratory tract.

4. FIRST AID MEASURES

EYES

Substrate Solution S-2772 / Factor Xa Solution:

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

SKIN

Substrate Solution S-2772 / Factor Xa Solution:

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

INGESTION

Substrate Solution S-2772:

give a glass of water. If necessary get a medical attention or contact the local Poison Control Center.

Factor Xa Solution:

give a glass of water or milk to drink. Get medical attention or contact the local Poison Control Center.

INHALATION

Substrate Solution S-2772 / Factor Xa Solution:

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

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.

Factor Xa Solution with Heparin

Animal serum test was tested for the presence of pathologies and found negative. Animal serum was treated during the production processes to inactive viruses. However these reagents should be handled with care as potentially infectious biological sample. Wear personal protective equipment.

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 Solution S-2772</u>	<u>Factor Xa Solution with Heparin</u>
Appearance:	liquid	liquid
Colour:	colourless	colourless
Odour:	odourless	odourless
Density:	not available	not available
pH:	4.1-4.3 at 20-25°C	8.1-8.3 at 20-25°C

BASIC PHYSICAL PROPERTIES

VAPOUR PRESSURE: not determined

SPECIFIC GRAVITY: not determined

SOLUBILITY (H₂O): 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 Solution S-2772 / Factor Xa Solution: harmful fumes of oxides of carbon and nitrogen may be formed during thermal decomposition.

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 Na₂ x 2H₂O: 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	November 2000	A. Lavezzari 