



Manufactured By: HYPHEN BioMed

MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION:

Name: HUMAN FACTOR Xa

Product number: AEZ007B / L

Kit composition: 1 x 100µg (AEZ007B) / Set of 6 x 100µg (AEZ007L).

Manufacturer: HYPHEN BioMed
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2. APPLICATION/INTENDED USE:

This reagent should be used only by suitable trained personnel, wearing the appropriate laboratory protective clothing, particularly eye and skin protection. It must be used according strictly to the instructions of package insert, and for the indicated purpose. The kit should be stored within the manufacturer's box at the specified temperature (2-8°C) and handled as per pack insert instructions.

The information provided in this material safety data sheet is believed to be correct and does not purport to be all inclusive and shall be used only as guide. HYPHEN BioMed and its appointed agents/distributors or OEM contractors shall not be held liable for any damage resulting from or from contact with the products included in the kit.

3. COMPOSITION/INFORMATION ON INGREDIENTS:

Vial containing purified human Factor Xa (about 100µg), lyophilised, with buffer and stabilizers:

Human factor Xa:	About 100 µg
Glycine:	< 30mg
Hepes:	< 10mg
Sodium chloride:	< 20mg
Bovine Serum albumin:	< 20 mg
Polyethylene glycol (PEG6000):	< 10mg
Prionex:	< 1%
Ciprofloxacin:	< 0.02%

4. TOXICITY HAZARDS:

Chemical compounds	CAS N°	% or weight	Classification	LD50 (oral)
Human factor Xa	NA	< 1 %	NA	NA
Glycine	50-40-6	< 50%	S22-24/25	NA
Hepes	7365-45-9	<15%	S22-24/25	unknown
Sodium chloride	7647-14-5	< 30%	NA	LD50 (rats) 3.75g/Kg
BSA	NA	< 30%	NA	NA
PEG 6000	25322-68-3	< 15%	R:36/38,S 26-36	LD50 (rats) 50 g/Kg
Prionex	NA	< 1%	NA	NA
Ciprofloxacin	NA	< 0.02%	NA	NA

5. HEALTH HAZARDS DATA:

All the above listed chemicals or biologicals may be harmful by inhalation, ingestion, or skin adsorption. Nasal irritation, eye reddening, and allergic reactions may result from overexposure.

- First aid:
- If swallowed, wash out mouth with water provided person is conscious. Medical advice is necessary.
 - In case of contact with eyes, flush with copious amounts of water, for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers.
 - In case of inhalation, remove victim to fresh air, and seek medical advice.
 - In any case of overexposure, call a physician.

Viral Safety: BSA was prepared from bovine plasma; which was tested for the absence of infectious agents, and collected from animals free from BSE. Human Factor Xa is from human plasma, which has been tested for HIV, HBs:Ag and HVC, with registered methods, and found negative. However, no test may totally exclude the absence of infectious agents. All biological sourced material should be treated as potentially hazardous and the appropriate handling and disposal procedures must be adhered to.

6. FIRE AND EXPLOSION HAZARD DATA:

Flammability: Restored solutions are aqueous and non-flammable. Lyophilised vial is non flammable, only carton boxes, dry chemical, interiors inserts are flammable.

Extinguishing Media: Carbon dioxide, dry chemical powder or appropriate foam.

Special fire fighting procedures: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin.

7. REACTIVITY DATA:

Stability: Stable

Hazardous combustion or decomposition products: Carbon monoxide, carbon dioxide, nitrogen oxide.

Hazardous polymerisation: Does not occur.

8. SPILL, LEAK AND DISPOSAL PROCEDURES:

Steps to be taken if material is released or spilled:

- Sweep up, place in a bag and hold for waste material. Avoid raising dust. Ventilate area and wash spill site after material pickup is complete.
- Waste disposal method:
Comply with all federal, state and local environmental regulations on waste handling and disposal.

9. ECOLOGY INFORMATION:

Do not empty into waters or drains.

10. PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE:

Must be only used by suitable trained and informed personnel.

Wear chemical resistant gloves, chemical safety goggles and protective laboratory clothing.

11. TOXICOLOGICAL INFORMATION:

This reagent is intended for in vitro research use only, by experienced and suitably trained personnel. There is no special risk when used in these conditions. Products may be toxic following skin or eye contact, inhalation or ingestion. For toxicity of components, refer to chapters 4 and 5.

12. WASTE DISPOSAL CONSIDERATIONS:

Any waste product or reagent must be discarded according to local considerations.
Do not reuse vials or containers.
"Biohazard" risk is mentioned on the insert.

13. PHYSICAL AND CHEMICAL PROPERTIES:

Lyophilized powder.
It does not present any specific physical or chemical reactivity (stable compound).

14. TRANSPORT AND STORAGE INFORMATION:

This reagent must be shipped adequately packaged and protected from any break during transportation.

It can be shipped at ambient temperature for a short period, not exceeding 7 days. It must be stored in a cold room at 2-8°C upon receipt.

No special regulation for transporting this product.

General rules for in vitro research should apply.

Local, State and Federal regulations for this kind of product must be respected.

The reagent must be stored in an appropriate refrigerated area, specifically dedicated for in vitro research kits.

All the storage constraints are indicated on the labels and on the insert.

15. QUALITY MANAGEMENT INFORMATION:

This reagent is designed, manufactured, controlled and followed according to the quality management system (based on ISO 9001:2000 and ISO13485:2004) developed by HYPHEN BioMed.

16. OTHER INFORMATION:

For in vitro research use only.

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