



HYPHEN BioMed

... a link between research and specialized applications for the biomedical diagnosis...

...un lien entre recherche et applications spécialisées pour le diagnostic biomédical...

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MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION:

Name: HEMOCLOT VII+X

Product number: CK051K

Kit composition: 6 vials of HEMOCLOT VII-X reagent, lyophilised (powder).

Manufacturer: HYPHEN BioMed
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2. APPLICATION/INTENDED USED:

This kit 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:

Hemoclot VII-X reagent: Freeze dried powder containing highly purified bovine prothrombin, fibrinogen and Factor V (<10%), hepes (<15%), glycine (<50%), sodium chloride (< 20%), ciprofloxacin (<0.001%), bovine serum albumine (BSA) (<20%)

4. TOXICITY HAZARDS:

Reagent	Chemical compounds	CAS N°	% of weight	Classification	LD50 (oral)
VII+X	Highly purified bovine prothrombin, fibrinogen, and Factor V	NA	<10%	NA	NA
	Glycine	50-40-6	<50%	S:22-24/25	NA
	Hepes	7365-45-9	< 15%	S 22'24 / 25	NA
	Sodium chloride	7647-14-5	< 20%	R36 S26	LD50(rats) 3.75 g/kg
	Ciprofloxacin	85721-33-1	< 0.001 %	NA	NA
	BSA	NA	<20%	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.

- 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.
- In case of contact, inhalation or ingestion of the reagent Hemoclot VII-X, seek immediately medical attention. If the victim is conscious, in case of ingestion, drink several glasses of water (or milk), to dilute contents of stomach. Do not induce vomiting.
- Bovine plasmas, used for the preparation of the purified proteins and of BSA contained in the Hemoclot VII-X kit, have been tested with registered methods. However, all bovine sourced material should be treated as potentially hazardous and the appropriate handling and disposal procedures must be adhered to, as no assay may totally exclude the presence of any infectious agent.

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6. FIRE AND EXPLOSION HARZAD DATA:

Flammability: Solutions are aqueous and 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 VII+X reagent into waters or drains. Comply with state and local environmental regulations. Usually wasted biological material is stocked in hermetic specific containers for incineration by specialized companies.

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.

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11. TOXICOLOGICAL INFORMATION:

All the components of the HEMOCLOT VII-X kit are intended for in vitro use only, by experienced and suitably trained personal. 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 box

13. PHYSICAL AND CHEMICAL PROPERTIES:

Reagents of the HEMOCLOT VII-X kit are lyophilized powder.

They do not present any specific physical or chemical reactivity, and are stable compounds.

14. TRANSPORT AND STORAGE INFORMATION:

The HEMOCLOT VII-X kit 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 diagnostic should apply.

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

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

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

15. REGULATORY INFORMATION:

This assay is designed, manufactured, controlled and followed according to the directive 98/79/CE from European parliament and council, (October 27th, 1998) related to the in vitro diagnostic medical device.

It is labelled with the CE mark.

Risk analysis has been performed and reduced to the lowest level available from the present knowledge.

16. OTHER INFORMATION:

For in vitro diagnostic use only.

Disclaimer: The information reported on this MSDS is believed to be accurate and represents the best information available to us. However, we make no warranty of merchantability or any other warranty, expressed or implied, with respect to such information, and we assure no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes.