



Manufactured By: HYPHEN BioMed

MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION:

Name: FACTOR V-L CALIBRATOR

Product number: ASC065K

Kit composition: 12 vials (3x4 levels) of human citrated plasma, presenting Activated Protein C Resistance (APC-R) at different levels, prediluted, lyophilised (powder).

Manufacturer: HYPHEN BioMed
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2. APPLICATION / INTENDED USE:

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:

Human citrated plasma: Freeze dried powder containing human plasma presenting APC-R (>50%), hepes (<3mg), glycine (<10mg), BSA (<10 mg), ciprofloxacin (<0.05%).

4. TOXICITY HAZARDS:

Reagents	Chemical compounds	CAS N°	% of weight	Classification	LD50 (oral)
Human	Human plasma	9001-26-7	>50 %	NA	NA
Citrated	Glycine	50-40-6	< 25%	S:22-24/25	NA
Plasma	Hepes	7365-45-9	< 10%	S 22'24 / 25	NA
	Ciprofloxacin	85721-33-1	< 0.05 %	NA	NA
	BSA	NA	<25%	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.
- In case of contact, inhalation or ingestion of any Plasma Calibrator, 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.

Viral Safety: - Human plasmas, used for the preparation of the kit, have been tested for HIV Antibodies, HBs:Ag and HCV Antibodies, with registered methods. However, all human 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.

- BSA was prepared from bovine plasma; which was tested for the absence of infectious agents, and collected from animals free from BSE. However, no test may totally exclude the absence of infectious agents. As any product of bovine origin, this reagent must be used with all the cautions required for handling a material potentially infectious.

6. FIRE AND EXPLOSION HAZARD DATA:

Flammability: 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 plasma 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.

11. TOXICOLOGICAL INFORMATION:

All the components of the 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 kit are lyophilized powder.
They do not present any specific physical or chemical reactivity, and are stable compounds.

14. TRANSPORT AND STORAGE INFORMATION:

The 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 kits 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.

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