



MATERIAL SAFETY DATA SHEET

ENGLISH

1. IDENTIFICATION

Name	Product number
BIOPHEN PLASMA CALIBRATOR	A222101
BIOPHEN VL Cal Undiluted	A222401
BIOPHEN NORMAL CONTROL PLASMA	A223201
BIOPHEN Act.PC-r CONTROL PLASMA	A223405
BIOPHEN NORMALPLASMA 2	A223602
BIOPHEN NORMALPLASMA 5	A223605

Application / Intended use

It must be used according strictly to the instructions of package insert, and for the indicated purpose.

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2. COMPOSITION / INFORMATION ON INGREDIENTS

Reagents	Chemical compounds	CAS N°	% or weight	Classification	LD50 (oral) rat
Human citrated plasma	H-plasma	NA	> 75 %	NA	NA
	Glycine	56-40-6	< 25%	S:22-24/25	7,9g/kg
	Hepes	7365-45-9	< 10 %	NA	2g/kg
	Ciprofloxacin	85721-33-1	< 0.01%	NA	NA

3. HEALTH HAZARDS IDENTIFICATION

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.

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.

4. FIRST AID MEASURES

-If swallowed, wash out mouth with water. 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. Seek medical advice.

-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 of the components of the kit, 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.

5. FIRE AND EXPLOSION HAZARDS 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.

6. SPILL, LEAK AND DISPOSAL PROCEDURES

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. Do not empty into drains or sinks.

Comply with all federal, state and local environmental regulations on waste handling and disposal

7. CAUTIONS TO BE TAKEN IN HANDLING AND STORAGE

Must be used only by suitable trained and informed personnel.

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

8. EXPOSURE CONTROLS, PERSONAL PROTECTION

Personal Protective Equipment

Eyes: Wear chemical splash goggles

Skin: Wear appropriate protective gloves to prevent skin exposure

Clothing: Wear appropriate protective clothing to prevent skin exposure

9. 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.

10. STABILITY AND REACTIVITY

Stability: Stable

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

Hazardous polymerisation: Does not occur.

11. TOXICOLOGICAL INFORMATION

All the components of the kits 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 2 and 3.

12. ECOLOGICAL INFORMATION

Do not empty reagents 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.

13. 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

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 use 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 use kits.

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

15. REGULATORY INFORMATION

These assays are designed, manufactured, controlled and followed according to the quality management system (based on ISO 9001 and ISO 13485) developed by HYPHEN BioMed, and 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.

Last revision date: 28/05/2008

Revision were made in sections: All

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.

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.