

MATERIAL SAFETY DATA SHEET

Last revision date: 17/12/2012

Printing date: 17/12/2012

Directive (CE) n°1907/2006

ENGLISH

1. PRODUCT & COMPANY IDENTIFICATION

Name	Product number	Presentation
Human Thrombin	EZ006A	100 NIH
	EZ006B	1000 NIH
	EZ0060	10 NIH
	EZ006K	set of 6x 10 NIH
	EZ006L	set of 10x 100 NIH

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. HEALTH HAZARDS IDENTIFICATION

Classification of reagent:

This reagent is not classified as dangerous according to the standard 67/548/CEE.

Others hazards:

Viral Safety: Purified human factors are extracted from human plasma, which has been tested for HIV Antibodies, HBs:Ag and HCV Antibodies, with registered methods. BSA and purified bovine factors were prepared from bovine plasma; which was tested for the absence of infectious agents, and collected from animals free from BSE. However, no biological test may totally exclude the presence of any infectious agent. All biological material should be treated as potentially hazardous and the appropriate handling and disposal procedures must be adhered to.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Reagent	Chemical compounds	CAS N°	% or weight	Classification	LD50 (oral) (rat)
H Thrombin	H Thrombin	NA	< 10%	NA	NA

4. FIRST AID MEASURES

-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 skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing.

-If swallowed, wash out mouth with water provided person is conscious, drink several glasses of water (or milk), to dilute contents of stomach. Do not induce vomiting. Medical advice is necessary.

-In case of inhalation, remove victim to fresh air, and seek medical advice.

-In any case of overexposure, call a physician.

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 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 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 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 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 use should apply.

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

The kits 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

This reagent is designed, manufactured, controlled and followed according to the quality management system (based on ISO 9001 and ISO 13485).

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

16. OTHER INFORMATION

For in vitro use only.

Revision were made in sections: Harmonisation of paragraph

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.

Diapharma Group, Inc. and its appointed agents or OEM contractors shall not be held liable for any damage resulting from or from contact with the products included in the kit.