

ABX Pentra SP Cal	A91A00743AEN	27/04/2010
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1. Product and company identification	
1.1. Identification of the product	
Product name:	ABX Pentra SP Cal
Product code:	Ref. HORIBA Medical: A11A01927
1.2. Use of the product	
Calibrator for the measurement of Specific Serum Proteins by immunoturbidimetry.	
1.3. Company identification	
	HORIBA ABX SAS - Rue du Caducée - Parc Euromédecine 34184 MONTPELLIER CEDEX 4 - FRANCE Tel: + 33 (0) 4 67 14 15 16 Fax: + 33 (0) 4 67 14 15 17 Email: documentation.med@horiba.com
1.4. Emergency phone number	
Company:	+ 800 67 14 15 16
French official advisory body:	ORFILA (INRS): + 33 (0) 1 45 42 59 59

2. Hazards identification	
Dangerous preparation according to 67/548/EEC - 99/45/EEC (Yes/No): No	
Most important hazards:	This product contains a substance with human origin. Hazardous properties cannot be excluded. The usual precautions taken when handling chemicals should be observed. Donors have been tested by FDA approved methods, test results turned out negative for antibodies to HIV-1 and HIV-2, non-reactive for HBsAg, and non-reactive for HCV. Even though tests on infectious diseases ended negative, this product should be handled as potentially infectious biomaterial.
Specific risks	May be harmful if swallowed. May cause irritations.

3. Composition/information on ingredients	
3.1. Description of the kit	
	CAL: 5 x 1 ml (RTU)
3.2. Hazardous ingredients (name, concentration)	
None	

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4. First-aid-measures

Inhalation:	None determined.
Skin contact:	Remove contaminated clothing. In case of contact, immediately flush skin with soap and copious amounts of cool water. Seek medical attention in case of skin reactions.
Eye contact:	Immediately wash eyes, also under the eyelids, with water for at least 15 minutes. Seek the attention of an ophthalmologist in case of troubles or persistent symptoms.
Ingestion:	Rinse mouth thoroughly with water. Induce vomiting. Have the patient drink large quantity of water, with active charcoal if possible. Seek medical attention.

5. Fire-fighting measures

Extinguishing media:	Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.
Specific risks:	None determined.
Special protective equipment:	None determined.
Additional recommendations:	None.

6. Accidental release measures

Personal precautions:	Wear personal protection equipment. Avoid contact with the substance. Provide adequate ventilation.
Environmental precautions:	Prevent from getting into soil, waterbodies and drains.
Methods for cleaning/absorption:	Soak up with absorbent materials such as sand, siliceous earth, acid- or universal binder. Store in special closed containers and dispose of according to local regulations. Wash contaminated area with disinfectant (sodium hypochlorite 0.5%).

7. Handling and storage

7.1. Handling

Technical measures:	Provide adequate ventilation, and local exhaust as needed.
Precautions:	The usual laboratory precautions should be observed.
Handling recommendations:	For use only by qualified technical staff. Wear a lab coat, protective gloves and safety goggles. Avoid contact with skin, eyes, and clothing. Do not inhale substance. After worktime and during work intervals the affected skin areas must be thoroughly cleaned. This product contains a substance with human origin. Even though tests on infectious diseases ended negative, this product should be handled as potentially infectious biomaterial.

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7.2. Storage

Technical measures:	None determined.
Storage conditions:	Store protected from light, in tightly closed containers, under a cool condition (2-8°C). Do not freeze the reagents. Protect from light. Keep sterile.
Incompatible materials:	No special requirements.
Packaging materials:	No special requirements.

8. Exposure controls/personal protection

8.1. Exposure limit values

None

8.2. Exposure controls

8.2.1. Occupational exposure controls

Technical measures:	Follow Standard Laboratory Practices concerning manipulation of human origin products.
Respiratory protection:	Provide adequate ventilation.
Hand protection:	Protective gloves according to EN 374. Glove material: Nitril rubber. Breakthrough time: >480 min. Observe glove manufacturer's instructions concerning penetrability and breakthrough time.
Eye protection:	Tightly sealed safety glasses according to EN 166.
Skin protection:	Lab coat.
Hygiene measures:	Change contaminated clothing. Wash hands before breaks and at the end of the work. Have eye wash bottle or eye rinse ready at work place.

8.2.2. Environmental exposure controls

Not available.

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9. Physical and chemical properties

9.1. General information

Physical state:	Liquid.		
Colour:	Yellowish up to brown, clear up to opalescent	Odour:	Odourless

9.2. Important health, safety and environmental information

pH:	7.10 - 7.25 (20°C)	Relative density:	1.01 - 1.06 g/mL (20°C)
Boiling point:	Not available	Solubility in water:	Fully miscible
Flash point:	Not combustible	Partition coefficient:	Not available
Flammability (solid, gaz):	Not available	Viscosity:	Not available
Explosive properties:	Not available	Vapour density:	Not available
Oxidizing properties:	Not available	Evaporation rate:	Not available

10. Stability and reactivity

Conditions to avoid:	Protect against heat/sun rays.
Materials to avoid:	Strong acids and alkalis. This reagent contains less than 0.1% of sodium azide as preservative. Sodium azide may react with Pb and Cu and form dangerous material, metal azide product.
Hazardous decomposition products:	None.
Other data:	No hazardous reactions known when used appropriately.

11. Toxicological information

Acute toxicity:	Not determined.
Chronic toxicity:	Not determined.
Inhalation:	Not determined.
Skin contact:	May cause irritations.
Eye contact:	May cause irritations.
Ingestion:	May be harmful if swallowed.
Other data:	This product contains a substance with human origin. Hazardous properties cannot be excluded. Donors have been tested by FDA approved methods, test results turned out negative for antibodies to HIV-1 and HIV-2, non-reactive for HBsAg, and non-reactive for HCV.

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12. Ecological information	
12.1. Ecotoxicity:	Water hazard class: 1 = mild water pollutant
12.2. Mobility:	Not determined.
12.3. Degradability:	Not determined.
12.4. Bioaccumulative potential:	Not determined.
12.5. Results of PBT assesment:	Not determined.
12.6. Other hazardous effects:	Do not allow to enter ground water, sewage or drains.

13. Disposal considerations	
Surplus or waste (residues) Contaminated packaging	Autoclave before disposal. It is advisable to avoid or reduce the generation of waste products wherever possible. Empty containers may contain product residues. Discard all waste, unused products, and contaminated packaging in accordance with current legislation. If you are in any doubt over the regulations, further information can be obtained from the competent authorities.

14. Transport information (International regulations)		
General information:	Not a hazardous material with respect to transportation regulations.	
By air (IATA):	Appropriate shipping name: UN number: Risk category: Packing group:	Not restricted.
By land (European ADR):	Shipping name: UN number: Risk category: Packing group:	Not restricted.
By sea (IMDG):	Shipping name: UN number: Risk category: Packing group: Marine polluante:	Not restricted.

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15. Regulatory information		
Symbols:	None	
R phrases:	None	
S phrases:	None	
Substances:	None	
Other regulatory requirements:	In no way does this information exempt the user from knowing about or applying all the national or international regulations relating to his/her activity.	

16. Other information		
16.1. List of relevant R phrases		
None		
16.2. Recommended restriction on use		
See specific information given in the product user information.		
16.3. Further information		
<p>This sheet is a complement to instructions for use but does not replace them. Information contained herewith is based on our current knowledge of the product, at the date shown, and is correct to best of our knowledge.</p> <p>Furthermore, the user's attention is drawn to the danger of using this product for anything other than its intended use. The user must accept the sole responsibility and take precautions accordingly for the use of this product.</p>		
16.4. Sources of key data		
This document has been compiled with information extracted from documents given by our raw material suppliers.		
16.5. Revision		
The section that have been modified from the previous version are indicated by vertical line on the left side of the table.		