

ABX Pentra Enzymatic Creatinine CP	A91A00735AEN	05/10/2009
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1. Product and company identification	
1.1. Identification of the product	
Product name:	ABX Pentra Enzymatic Creatinine CP
Product code:	Ref. HORIBA Medical: A11A01907
1.2. Use of the product	
Diagnostic reagent for quantitative <i>in-vitro</i> determination of creatinine in serum, plasma and urine by colorimetry.	
1.3. Company identification	
	HORIBA ABX SAS - Rue du Caducée - Parc Euromédecine 34184 MONTPELLIER CEDEX 4 - FRANCE Tel: (33) 4 67 14 15 16 Fax: (33) 4 67 14 15 17 Email: documentation.med@horiba.com
1.4. Emergency phone number	
	Contact the nearest first-aid station

2. Hazards identification	
Dangerous preparation according to 67/548/EEC - 99/45/EEC (Yes/No): No	
Most important hazards:	The usual precautions taken when handling chemicals should be observed. REAGENT 1 : This preparation contains a small concentration of chloramphenicol which may cause cancer. Avoid contact with eyes and skin. Do not ingest or inhale.
Specific risks	None.

3. Composition/information on ingredients						
3.1. Description of the kit						
	REAGENT : Bi-reagent cassette REAGENT 1 : 1 x 22 ml (Start reagent) REAGENT 2 : 1 x 8 ml (Enzyme reagent)					
3.2. Hazardous ingredients (name, concentration)						
CAS N.	EC N.	Name	Concentration	Symbol	Risk	Registration number
56-75-7	200-287-4 (EINECS)	REAGENT 1 : Chloramphenicol Detergent	< 0.1% < 1%	T Xi	R43, R45, R63, R68 R36/38	_____
26628-22-8	247-852-1 (EINECS)	REAGENT 2 : Sodium azide	< 0.1%	T+, N	R28, R32, R50/53	_____

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4. First-aid-measures

Inhalation:	If inhaled, remove victim to fresh air. If breathing is difficult or if cough or other symptoms develop seek medical attention.
Skin contact:	In case of contact, immediately flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.
Eye contact:	In case of contact, immediately flush eyes with plenty of tepid water while separating eyelids with fingers, removing contact lenses if worn. Continue to flush for at least 15 minutes. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.
Ingestion:	If ingested, contact a poison control center or physician for instructions.

5. Fire-fighting measures :

Extinguishing media:	Use whatever is required (carbon dioxide, chemical foam, dry chemical or water spray) for the surrounding area.
Specific risks:	Irritating and/or toxic gases may be emitted upon the product's decomposition.
Special protective equipment:	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.
Additional recommendations:	None

6. Accidental release measures

Personal precautions:	Wear a lab coat, protective gloves and safety goggles. Avoid physical contact with material and avoid vapor inhalation. After handling, immediately wash any areas of the body that may have been exposed, whether or not known skin contact has occurred.
Environmental precautions:	Prevent from getting into sewage, water, ground.
Methods for cleaning/absorption:	Collect liquid in an appropriate container or absorb with an inert materials and place in waste container. Wash surrounding area. Dispose of according to local regulations.

7. Handling and storage

7.1. Handling

Technical measures:	Avoid contact with skin, eyes or clothing. Wash thoroughly after handling. Wash contaminated clothing before reuse.
Precautions:	The usual laboratory precautions should be observed.
Handling recommendations:	Avoid contact. Wear a lab coat, protective gloves and safety goggles.

7.2. Storage

Technical measures:	None determined.
Storage conditions:	Store at 2-8°C.
Incompatible materials:	None determined.
Packaging materials:	None determined.

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8. Exposure controls/personal protection

8.1. Exposure limit values

Specific control parameters:	None determined.
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8.2. Exposure controls

8.2.1. Occupational exposure controls

Technical measures:	Local exhaust not required under normal circumstances.
Respiratory protection:	A full-facepiece respirator with formaldehyde vapor cartridges selected to provide a filtration efficiency appropriate to your workplace is recommended.
Hand protection:	Impermeable gloves.
Eye protection:	Safety goggles and face shield.
Skin protection:	Lab coat.
Hygiene measures:	Change contaminated clothes. Wash hands before and after use.

8.2.2. Environmental exposure controls

Not available.

9. Physical and chemical properties

9.1. General information

Physical state:	<u>REAGENT 1</u> : Liquid <u>REAGENT 2</u> : Liquid		
Colour:	<u>REAGENT 1</u> : Light yellow <u>REAGENT 2</u> : Light brown	Odour:	<u>REAGENT 1</u> : Not determined <u>REAGENT 2</u> : Odourless

9.2. Important health, safety and environmental information

pH:	<u>REAGENT 1</u> : 7 - 8 <u>REAGENT 2</u> : 7 - 8	Relative density:	Not available
Boiling point:	Not available	Solubility:	Soluble
Flash point:	Not available	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

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10. Stability and reactivity	
Conditions to avoid:	None known.
Materials to avoid:	Sodium azide may react with Pb and Cu and form dangerous material, metal azide product.
Hazardous decomposition products:	Thermal decomposition can lead to release of irritating gases and vapors.
Other data:	No hazardous reactions known when used appropriately.

11. Toxicological information	
Acute toxicity:	Not determined.
Chronic toxicity:	Exposure to chloramphenicol may cause leukemia, a cancer of the blood or bone marrow. It may disrupt the bone marrow's production of blood cells (aplastic anemia). Repeated exposure to chloramphenicol may damage the liver. Target Organs: Chloramphenicol: blood, immune system(skin) and liver.
Inhalation:	Although there is no evidence that the enzyme(s) in this preparation induces specific respiratory hypersensitivity, all proteins are potential respiratory allergens and may result in respiratory sensitization in certain individuals after repeated and/or prolonged inhalation exposure, producing mild to severe symptoms similar to pollen allergy or asthma, including
Skin contact:	May cause irritation, redness and discomfort.
Eye contact:	May cause irritation, redness, watering and itching. May cause systemic effects.
Ingestion:	Effects of ingestion are unknown, but may include digestive system irritation, nausea, vomiting or diarrhea.
Other data:	Quantitative data about the toxicity of the product are not available. Dangerous properties cannot be excluded. However, risks are not to be expected when the product is handled by qualified and authorized personnel with the necessary precautions for chemicals/diagnostic reagents.

12. Ecological information	
12.1. Ecotoxicity:	Not determined.
12.2. Mobility:	Not determined.
12.3. Degradability:	Not determined.
12.4. Bioaccumulative potential:	Not determined.
12.5. Results of PBT assessment:	Not determined.
12.6. Other hazardous effects:	Quantitative data on ecological effects of the product are not available.

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13. Disposal considerations

Surplus or waste (residues):	REAGENT 2 contains less than 0.1% sodium azide as a preservative. As sodium azide may react with lead and copper, to form explosive metal azides, this reagent should be disposed of by flushing with copious amounts of water. The products must be disposed of as a laboratory chemical according to local regulations.
Contaminated packaging:	Type of primary container: plastic cassette composed of polyethylene high density. Packaging must be disposed of according to local regulations.

14. Transport information (International regulations)

By air (IATA):	Appropriate shipping name: UN number: Risk category: Packing group:	Not applicable
By land (European ADR):	Shipping name: UN number: Risk category: Packing group:	Not applicable
By sea (IMDG):	Shipping name: UN number: Risk category: Packing group: Marine polluante:	Not applicable

15. Regulatory information

Symbols:	None	
R phrases:	None	
S phrases:	None	
Substances:	None	
Specific provisions and related laws:	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

R28	Very toxic if swallowed.
R32	Contact with acids liberates very toxic gas.
R36/38	Irritating to eyes and skin.
R43	May cause sensitisation by skin contact.
R45	May cause cancer.

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R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R63	Possible risk of harm to the unborn child.
R68	Possible risk of irreversible effects.

16.2. Recommended restriction on use

See specific information given in the product user information.

16.3. Further information

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 the best of our knowledge.
Furthermore, the user's attention is drawn to the dangers 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.

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 sections that have been modified from the previous version are indicated by a vertical line on the left side of the table.