

ABX Pentra HDL Direct CP	A91A00577DEN	14/10/2009
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1. Product and company identification	
1.1. Identification of the product	
Product name:	ABX Pentra HDL Direct CP
Product code:	Ref. HORIBA Medical : A11A01636
1.2. Use of the product	
Diagnostic reagent for quantitative <i>in-vitro</i> determination of High-Density Lipoprotein Cholesterol (HDL -C) in human serum or plasma 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:	It is recommended to handle this product in accordance with the Standard Laboratory Precautions.
Specific risks	<p>Potential Health Effects:</p> <p>Inhalation: Inhalation of enzyme dust or aerosols may induce respiratory sensitization and may cause allergic reactions in sensitized individuals after repeated exposure. Mild to severe symptoms, similar to pollen allergy or asthma, may include mucous membrane or eye irritation, itching of the skin or eyes, sneezing, nasal or sinus congestion, coughing, wheezing and tightness in the chest. These symptoms may develop as late as 12 hours after exposure.</p> <p>Eye: No data available. Eye exposure may cause irritation, redness and itching.</p> <p>Skin: No data available. Skin contact may cause irritation, redness and discomfort.</p> <p>Ingestion: No data available.</p> <p>Chronic Effects: No data available.</p>

3. Composition/information on ingredients	
3.1. Description of the kit	
	<p>REAGENT 1 Bi-reagent cassette</p> <p>REAGENT 1 1 x 62 ml : Good's buffer, Cholesterol oxidase (<1000 U/l), Peroxidase (<1300 ppg U/l), N,N-bis(4-sulfobutyl)-toluidine, disodium (<1mM), Accelerator (<1 mM), Preservative (<0.1%), Ascorbic acid oxidase (<3000 U/l)</p> <p>REAGENT 2 1 x 21 ml : Good's buffer, Cholesterol esterase (<1500 U/l), 4-amino-antipyrine (<1 mM), Detergent (1-2%), Preservative (<1%)</p>

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3.2. Hazardous ingredients (name, concentration)

CAS N.	Name	Concentration	Symbol	Risk	Registration number
Trade secret Mixture	REAGENT 1: Proprietary non-ionic detergent Proprietary preservative	< 1% (wt/wt) < 0.1% (wt/wt)	Xn, N C, N	R22, R38, R41, R52 R10, R20/21/22, R34, R43, R50/53	- -
Trade secret Mixture	REAGENT 2: Proprietary non-ionic detergent Proprietary preservative	1-2% (wt/wt) < 1% (wt/wt)	Xn, N C, N	R22, R38, R41, R52 R10, R20/21/22, R34, R43, R50/53	- -

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:	In case of ingestion, contact a poison control center or physician for instructions.

5. Fire-fighting measures : Product non flammable

Extinguishing media:	Use extinguishing media suitable for surrounding fire such as dry chemical, water spray, carbone dioxide or chemical foam.
Specific risks:	None determined.
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. Wash hands thoroughly after handling.
Environmental precautions:	No information available.
Methods for cleaning/absorption:	Absorb spill with inert material. Decontaminate the spill site following standard procedures. Dispose of according to local regulations.

7. Handling and storage

7.1. Handling

Technical measures:	No special requirements.
Precautions:	The usual laboratory precautions should be observed.
Handling recommendations:	Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

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7.2. Storage

Technical measures:	No special requirements.
Storage conditions:	Store at 2-8°C.
Incompatible materials:	Do not store with incompatible substances (see Section 10).
Packaging materials:	No special requirements.

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:	Use general room ventilation.
Respiratory protection:	A respirator is not required under normal conditions of use.
Hand protection:	Protective gloves.
Eye protection:	Safety goggles.
Skin protection:	Lab coat. Remove contaminated clothing promptly.
Hygiene measures:	Change contaminated clothes. Wash hands before and after use.

8.2.2. Environmental exposure controls

Not applicable.	
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9. Physical and chemical properties

9.1. General information

Physical state:	Liquid						
Colour:	<table border="1"> <tr> <td>REAGENT 1</td> <td>Clear pale yellow</td> </tr> <tr> <td>REAGENT 2</td> <td>Clear light brown</td> </tr> </table>	REAGENT 1	Clear pale yellow	REAGENT 2	Clear light brown	Odour:	Odorless (both reagents)
REAGENT 1	Clear pale yellow						
REAGENT 2	Clear light brown						

9.2. Important health, safety and environmental information

pH:	6.0 (both reagents)	Relative density:	Not determined
Boiling point:	Not determined	Solubility:	Soluble in water (both reagents)
Flash point:	Not determined	Partition coefficient:	Not determined
Flammability (solid, gaz):	Not determined	Viscosity:	Not determined
Explosive properties:	Not determined	Vapour density:	Not determined
Oxidizing properties:	Not determined	Evaporation rate:	Not determined

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9.3. Other information	
None.	

10. Stability and reactivity	
Conditions to avoid:	There are no physical conditions known to result in a hazardous situation.
Materials to avoid:	Avoid strong oxidizing agents, strong acids and bases.
Hazardous decomposition products:	None expected under normal conditions of use.
Other data:	Stable under ordinary conditions of use and storage. Hazardous polymerization will not occur.

11. Toxicological information	
Acute toxicity:	Toxicological Data:4-Aminoantipyrine (CAS# 83-07-8): oral LD50 rat: 1700 mg/kg
Chronic toxicity:	Not available.
Inhalation:	Not available.
Skin contact:	Not available.
Eye contact:	Not available.
Ingestion:	Not available.
Other data:	Not available.

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.

13. Disposal considerations	
Surplus or waste (residues):	Unused product, spilled material and waste 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.

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14. Transport information (International regulations)	
General information:	Not applicable.
By air (IATA):	Not applicable.
By land (ADR):	Not applicable.
By sea (IMDG):	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	
R10 R22 R20/21/22 R34 R38 R41 R43 R52 R50/53	Flammable. Harmful if swallowed. Harmful by inhalation, in contact with the skin and if swallowed. Causes burns. Irritating to skin. Risk of serious damage to eyes. May cause sensitisation by skin contact. Harmful to aquatic organisms. Very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment.
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.	