

ABX Pentra LDL Cal	A91A00600CEN	15/06/2010
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1. Product and company identification	
1.1. Identification of the product	
Product name:	ABX Pentra LDL Cal
Product code:	Ref. HORIBA Medical: A11A01678
1.2. Use of the product	
Calibrator for the measurement of Low Density Lipoprotein Cholesterol (LDL-C).	
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): Yes	
Most important hazards:	Xn - harmful
Precautionary statement:	The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Avoid contact with eyes and skin. Do not ingest or inhale. Human source material. Treat as potentially infectious. Each serum donor unit used in the preparation of this product has been tested by an FDA approved method and found non-reactive for the presence of HbsAg, HCV and antibody to HIV 1/2. Because no known test method can offer complete assurance that infectious agents are absent, all human-based products should be handled in accordance with good laboratory practices using appropriate precautions.
Specific risks	R22, R52/53

3. Composition/information on ingredients	
3.1. Description of the kit	
	CAL : 2 x 1 ml (Lyophilised)

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3.2. Hazardous ingredients (name, concentration)

CAS N.	EC N.	Name	Concentration	Symbol	Risk	Registration number
-	-	Human serum	> 99 %	None	None	-
26628-22-8	247-852-1 (EINECS)	Sodium azide	0.3 %	T+, N	R28, R32, R50, R53	-

4. First-aid-measures

Inhalation:	If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.
Skin contact:	Remove contaminated clothing. In case of contact, immediately flush skin with copious amounts of cool water. Seek medical attention in case of skin reactions.
Eye contact:	Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. 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 instruction.

5. Fire-fighting measures

Extinguishing media:	Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.
Specific risks:	Irritating or highly toxic gases may be generated by combustion, including carbon monoxide (CO), carbon dioxide (CO ₂) and nitrogen oxides (NO _x).
Special protective equipment:	Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.
Additional recommendations:	None.

6. Accidental release measures

Personal precautions:	Wear Personal Protective Equipment (PPE) as indicated in section 8 (Exposure controls/personal protection). Avoid physical contact with material. Wash hands thoroughly after handling.
Environmental precautions:	This preparation contains a small amount of sodium azide. Sodium azide is harmful to aquatic organisms and can react with copper, lead, brass or solder in plumbing system and form potentially explosive metal azides. Prevent preparation from entering the drain and water intakes in the environment. If preparation enters the drain, flush with large amounts of water to prevent azide build up. Follow proper disposal procedures.
Methods for cleaning/absorption:	Scoop spilled powder into suitable container for disposal. Decontaminate the spill site following standard procedures for biohazardous spills. Dispose of materials according to local regulations.

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7. Handling and storage

7.1. Handling

Technical measures:	Facilities storing or using this preparation should be equipped with an eyewash fountain.
Precautions:	The usual laboratory precautions should be observed.
Handling recommendations:	Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

7.2. Storage

Technical measures:	No special requirements.
Storage conditions:	Store at 2°C to 8°C.
Incompatible materials:	Incompatible with acids, with some metals. Forms explosion-sensitive compounds.
Packaging materials:	No special requirements.

8. Exposure controls/personal protection

8.1. Exposure limit values

CAS N.	Chemical name	Type	Value
26628-22-8	Sodium azide	ACGIH - Threshold Limits Values - Ceilings (TLV-C) Canada - Quebec - Occupational Exposure Limits - Ceilings EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - Skin Notations EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - STELs EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - TWAs Germany - DFG - Recommended Exposure Limits - Ceilings (Peak Limitations) Germany - DFG - Recommended Exposure Limits - MAK Values Germany - TRGS 900 - Occupational Exposure Limits - TWAs Israel - Occupational Exposure Limits - Ceilings Korea - Occupational Exposure Limits - Ceilings	0.29 mg/m ³ Ceiling (as NaN ₃); 0.11 ppm Ceiling (vapor, as hydrazoic acid) 0.3 mg/m ³ Ceiling; 0.11 ppm Ceiling Possibility of significant uptake through the skin 0.3 mg/m ³ STEL 0.1 mg/m ³ TWA 0.4 mg/m ³ Peak (inhalable fraction) 0.2 mg/m ³ MAK (inhalable fraction) 0.2 mg/m ³ TWA (exposure factor 2) 0.29 mg/m ³ Ceiling (as NaN ₃); 0.11 ppm Ceiling (vapor, as Hydrazoic acid) 0.1 ppm Ceiling; 0.3 mg/m ³ Ceiling

8.2. Exposure controls

8.2.1. Occupational exposure controls

Specific control parameters:	No special requirements.
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Technical measures:	No special requirements.
Respiratory protection:	A respirator is not required under normal conditions of use.
Hand protection:	Wear chemical resistant protective gloves.
Eye protection:	Wear appropriate protective chemical safety glasses.
Skin protection:	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
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.	

9. Physical and chemical properties

9.1. General information

Physical state:	Pellet		
Colour:	Pale yellow	Odour:	Odourless

9.2. Important health, safety and environmental information

pH:	Not applicable	Relative density:	Not available
Boiling point:	Not applicable	Solubility in water:	soluble
Flash point:	Not applicable	Partition coefficient:	Not available
Flammability (solid, gaz):	Not available	Viscosity:	Not applicable
Explosive properties:	Not available	Vapour density:	Not applicable
Oxidizing properties:	Not available	Evaporation rate:	Not applicable

10. Stability and reactivity

Conditions to avoid:	There are no physical conditions known to result in a hazardous situation.
Materials to avoid:	Acids, some metals. This reagent contains sodium azide as preservative. Sodium azide may react with Pb and Cu and form dangerous material, metal azide product.
Hazardous decomposition products:	None expected under normal conditions of use.
Other data:	Hazardous polymerisation will not occur.

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11. Toxicological information

Acute toxicity:	Sodium azide (CAS N. 26628-22-8): Oral LD50 Rat: 27 mg/kg; Dermal LD50 Rabbit: 20 mg/kg
Chronic toxicity:	Not determined.
Inhalation:	Not determined.
Skin contact:	Not determined.
Eye contact:	Not determined.
Ingestion:	Not determined.
Other data:	Human source material present. Although the product was found negative to Hepatitis-B surface antigen and antibodies to HIV 1/2 and HCV, it should be handled at Biosafety Level 2 as recommended for any potentially infectious serum specimen. The toxicological properties have not been thoroughly investigated. Not classified as a human carcinogen (ACGIH - Threshold Limits values)

12. Ecological information

12.1. Ecotoxicity:	Fresh water fish species data on sodium azide (CAS N. 26628-22-8): 96 Hr LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 Hr LC50 Lepomis macrochirus: 0.7 mg/L; 96 Hr LC50 Pimephales promelas: 5.46 mg/L [flow-through].
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:	Not determined.

13. Disposal considerations

Surplus or waste (residues) Contaminated packaging	Do not pour this preparation down the drain. 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. Waste classification of sodium azide (CAS N. 26628-22-8): U.S. - California - 22 CCR - Presumed Hazardous Wastes: Ignitable; Reactive U.S. - RCRA (Resource Conservation & Recovery Act) - P Series Wastes - Acutely Toxic Wastes: waste number P105
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14. Transport information (International regulations)

General information:	Not classified as dangerous goods. Not regulated per IATA and DOT 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.

15. Regulatory information

Symbols:	Xn	Harmful
R phrases:	R22 R52/53	Harmful if swallowed Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
S phrases:	S45 S61	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible) Avoid release to the environment. Refer to special instructions/safety data sheets.
Substances:	Sodium azide	CAS N° 26628-22-8
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

R22	Harmful if swallowed.
R28	Very toxic if swallowed.
R32	Contact with acids liberates very toxic gas.
R50	Very toxic to aquatic organisms.
R53	May cause long-term adverse effects in the aquatic environment.
R52/53	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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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 best of our knowledge.
 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.

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.