

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Product name : ABX Pentra HDL Cal
Product code : A11A01647
Product description : 2 X 1 mL (Lyophilised)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Calibrator for the measurement of high-density lipoprotein cholesterol (HDL-C) by colorimetry

1.3 Details of the supplier of the safety data sheet

HORIBA ABX SAS
 Parc Euromédecine - Rue du Caducée
 BP 7290
 34184 MONTPELLIER CEDEX 4 - FRANCE
 Tel: +33 (0) 4 67 14 15 16
 Fax: +33 (0) 4 67 14 15 17

e-mail address of person responsible for this SDS : documentation.med@horiba.com

1.4 Emergency telephone number**National advisory body/Poison Centre**

Telephone number United Kingdom (UK) : +44 (0)20 7771 5310

Supplier

Telephone number : + 800 67 14 15 16

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture**

Product definition : Mixture

Classification according to Directive 1999/45/EC [DPD]

The product is classified as dangerous according to Directive 1999/45/EC and its amendments.

Classification : Xn; R22
 R52/53

Human health hazards : Harmful if swallowed.

Environmental hazards : Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

See Section 16 for the full text of the R phrases or H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Hazard symbol or symbols :



Indication of danger : Harmful

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SECTION 2: Hazards identification

- Risk phrases** : R22- Harmful if swallowed.
R52/53- Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- Safety phrases** : Not applicable.
- Hazardous ingredients** : sodium azide
- Supplemental label elements** : Not applicable.

2.3 Other hazards

- Other hazards which do not result in classification** : Not available.
- Biological Hazard** : 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.

SECTION 3: Composition/information on ingredients

Substance/mixture : Mixture

| Product/ingredient name | Identifiers | % | Classification | | Type |
|-------------------------|---|--------|---|---|---------|
| | | | 67/548/EEC | Regulation (EC) No. 1272/2008 [CLP] | |
| sodium azide | EC: 247-852-1 CAS: 26628-22-8 Index: 011-004-00-7 | 0,25-1 | T+; R28 R32 N; R50/53 See Section 16 for the full text of the R-phrases declared above. | Acute Tox. 2, H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 See Section 16 for the full text of the H statements declared above. | [1] [2] |

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs or vPvBs or have been assigned a workplace exposure limit and hence require reporting in this section.

Type

- [1] Substance classified with a health or environmental hazard
 [2] Substance with a workplace exposure limit
 [3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII
 [4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII

Occupational exposure limits, if available, are listed in Section 8.

SECTION 4: First aid measures

4.1 Description of first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.

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SECTION 4: First aid measures

- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

4.2 Most important symptoms and effects, both acute and delayed**Potential acute health effects**

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : Harmful if swallowed.

Over-exposure signs/symptoms

- Eye contact** : No specific data.
- Inhalation** : No specific data.
- Skin contact** : No specific data.
- Ingestion** : No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : No specific treatment.

SECTION 5: Firefighting measures

- Flammability** : May be combustible at high temperature.

5.1 Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

5.2 Special hazards arising from the substance or mixture

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SECTION 5: Firefighting measures

Hazards from the substance or mixture : No specific fire or explosion hazard.

Hazardous thermal decomposition products : No specific data.

5.3 Advice for firefighters

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. This material is harmful to aquatic organisms. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also Section 8 for additional information on hygiene measures.

6.2 Environmental precautions

: Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material.

Other information : 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.

6.3 Methods and materials for containment and cleaning up

Small spill : Move containers from spill area. Vacuum or sweep up material and place in a designated, labelled waste container. Dispose of via a licensed waste disposal contractor.
Wash contaminated area with disinfectant.

Large spill : Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labelled waste container. Dispose of via a licensed waste disposal contractor.

6.4 Reference to other sections

: See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

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SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

- : Store between the following temperatures: 2 to 8°C (35,6 to 46,4°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.

- Recommendations** : Due to sodium azide, incompatible with acid and some metals. Forms explosion-sensitive compounds.

7.3 Specific end use(s)

- Recommendations** : Not available.
- Industrial sector specific solutions** : Not available.

SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

8.1 Control parameters

Occupational exposure limits

| Product/ingredient name | Exposure limit values |
|-------------------------|---|
| sodium azide | EH40/2005 WELs (United Kingdom (UK), 1/2012). Absorbed through skin. STEL: 0,3 mg/m ³ , (as NaN ₃) 15 minute(s). TWA: 0,1 mg/m ³ , (as NaN ₃) 8 hour(s). |

- Recommended monitoring procedures** : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to European Standard EN 689 for methods for the assessment of exposure by inhalation to chemical agents and national guidance documents for methods for the determination of hazardous substances.

Derived effect levels

No DELs available.

Predicted effect concentrations

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SECTION 8: Exposure controls/personal protection

No PECs available.

8.2 Exposure controls

Appropriate engineering controls : No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants. If this product contains ingredients with exposure limits, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists or dusts.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties****Appearance**

| | |
|--|---|
| Physical state | : Solid. [Pellets.] |
| Colour | : Pale yellow |
| Odour | : Odourless. |
| Odour threshold | : Not available. |
| pH | : Not available. |
| Melting point/freezing point | : Not available. |
| Initial boiling point and boiling range | : Not available. |
| Flash point | : Not available. |
| Evaporation rate | : Not available. |
| Flammability | : May be combustible at high temperature. |

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SECTION 9: Physical and chemical properties

| | |
|---|---|
| Upper/lower flammability or explosive limits | : Not available. |
| Vapour pressure | : Not available. |
| Vapour density | : Not available. |
| Relative density | : Not available. |
| Solubility(ies) | : Soluble in the following materials: cold water and hot water. |
| Partition coefficient: n-octanol/water | : Not available. |
| Auto-ignition temperature | : Not available. |
| Decomposition temperature | : Not available. |
| Viscosity | : Not available. |
| Explosive properties | : Not available. |
| Oxidising properties | : Not available. |

9.2 Other information

No additional information.

SECTION 10: Stability and reactivity

| | |
|--|---|
| 10.1 Reactivity | : No specific test data related to reactivity available for this product or its ingredients. |
| 10.2 Chemical stability | : The product is stable. |
| 10.3 Possibility of hazardous reactions | : Under normal conditions of storage and use, hazardous reactions will not occur. |
| 10.4 Conditions to avoid | : No specific data. |
| Recommendations | : This reagent contains sodium azide as preservative. Sodium azide may react with Pb and Cu and form dangerous material, metal azide product. |
| 10.5 Incompatible materials | : No specific data. |
| 10.6 Hazardous decomposition products | : Under normal conditions of storage and use, hazardous decomposition products should not be produced. |

SECTION 11: Toxicological information**11.1 Information on toxicological effects****Acute toxicity**

| Product/ingredient name | Result | Species | Dose | Exposure |
|-------------------------|-----------|---------|----------|----------|
| sodium azide | LD50 Oral | Rat | 27 mg/kg | - |

Irritation/Corrosion

No known significant effects or critical hazards.

Sensitisation

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SECTION 11: Toxicological information

No known significant effects or critical hazards.

Mutagenicity

No known significant effects or critical hazards.

Carcinogenicity

No known significant effects or critical hazards.

Reproductive toxicity

No known significant effects or critical hazards.

Teratogenicity

No known significant effects or critical hazards.

Information on the likely routes of exposure : Not available.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.

Inhalation : No specific data.

Skin contact : No specific data.

Ingestion : No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure**Short term exposure**

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

No known significant effects or critical hazards.

General : No known significant effects or critical hazards.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

Other information : Not available.

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SECTION 11: Toxicological information

SECTION 12: Ecological information

12.1 Toxicity

| Product/ingredient name | Result | Species | Exposure |
|-------------------------|-----------------------------------|---|----------|
| sodium azide | Acute EC50 0,348 mg/L Fresh water | Algae - Pseudokirchneriella subcapitata | 96 hours |
| | Acute EC50 6,4 mg/L Fresh water | Crustaceans - Simocephalus serrulatus - Larvae - es7:k56s:7pt | 48 hours |
| | Acute EC50 4,2 mg/L Fresh water | Daphnia - Daphnia pulex - Larvae - es7:k56s:7pt | 48 hours |
| | Acute LC50 0,68 mg/L Fresh water | Fish - Lepomis macrochirus - 0,6 g | 96 hours |

12.2 Persistence and degradability

Conclusion/Summary : Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Mobility : Not available.

12.5 Results of PBT and vPvB assessment

PBT : Not applicable.

vPvB : Not applicable.

12.6 Other adverse effects : No known significant effects or critical hazards.

SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

Product

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Significant quantities of waste product residues should not be disposed of via the foul sewer but processed in a suitable effluent treatment plant. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Hazardous waste : The classification of the product may meet the criteria for a hazardous waste.

Packaging

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

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SECTION 13: Disposal considerations

Special precautions : This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

| | ADR/RID | ADN/ADNR | IMDG | IATA |
|-----------------------------------|----------------|----------------|----------------|----------------|
| 14.1 UN number | Not regulated. | Not regulated. | Not regulated. | Not regulated. |
| 14.2 UN proper shipping name | - | - | - | - |
| 14.3 Transport hazard class(es) | - | - | - | - |
| 14.4 Packing group | - | - | - | - |
| 14.5 Environmental hazards | No. | No. | No. | No. |
| 14.6 Special precautions for user | Not available. | Not available. | Not available. | Not available. |
| Additional information | - | - | - | - |

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions : Not applicable.
on the manufacture,
placing on the market and
use of certain dangerous
substances, mixtures and
articles

Other EU regulations

Europe inventory : All components are listed or exempted.

Black List Chemicals : Not listed

Priority List Chemicals : Not listed

Integrated pollution prevention and control list (IPPC) - Air : Not listed

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SECTION 15: Regulatory information

Integrated pollution prevention and control list (IPPC) - Water : Not listed

International regulations

Chemical Weapons Convention List Schedule I Chemicals : Not listed

Chemical Weapons Convention List Schedule II Chemicals : Not listed

Chemical Weapons Convention List Schedule III Chemicals : Not listed

15.2 Chemical Safety Assessment : This product contains substances for which Chemical Safety Assessments are still required.

SECTION 16: Other information

Revision comments : New MSDS form.

Indicates information that has changed from previously issued version.

Abbreviations and acronyms : ATE = Acute Toxicity Estimate
 CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
 DNEL = Derived No Effect Level
 EUH statement = CLP-specific Hazard statement
 PNEC = Predicted No Effect Concentration
 RRN = REACH Registration Number

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Aquatic Chronic 3, H412

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

| Classification | Justification |
|-------------------------|--------------------|
| Aquatic Chronic 3, H412 | Calculation method |

Full text of abbreviated H statements : H300 Fatal if swallowed.
 H400 Very toxic to aquatic life.
 H410 Very toxic to aquatic life with long lasting effects.
 H412 Harmful to aquatic life with long lasting effects.

Full text of classifications [CLP/GHS] : Acute Tox. 2, H300 ACUTE TOXICITY: ORAL - Category 2
 Aquatic Acute 1, H400 AQUATIC TOXICITY (ACUTE) - Category 1
 Aquatic Chronic 1, H410 AQUATIC TOXICITY (CHRONIC) - Category 1
 Aquatic Chronic 3, H412 AQUATIC TOXICITY (CHRONIC) - Category 3

Full text of abbreviated R phrases : R28- Very toxic if swallowed.
 R22- Harmful if swallowed.
 R32- Contact with acids liberates very toxic gas.
 R50/53- Very toxic to aquatic organisms, 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.

Full text of classifications [DSD/DPD] : T+ - Very toxic
 Xn - Harmful
 N - Dangerous for the environment

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SECTION 16: Other information

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Version : 1

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.