

MATERIAL SAFETY DATA SHEET

ABX Pentra Bilirubin, Direct CP - A91A00562

2002/12/02

1. Product and company identification

1.1 Identification of the product:

Product name: ABX Pentra Bilirubin, Direct CP

Product code: Ref. ABX ==> A11A01635

1.2 Company identification:

ABX Diagnostics - Rue du Caducée - Parc Euromédecine -
34184 MONTPELLIER CEDEX 4 - FRANCE

TEL (33) 4 67 14 15 16 FAX (33) 4 67 14 15 17

1.3 Emergency phone number:

Contact the nearest first-aid station.

2. Composition/information on ingredients

Description of the kit:

REAGENT 1: Bi-reagent cassette.

REAGENT 1 = 1 × 22 ml + **REAGENT 2** = 1 × 6 ml

Chemical nature:

REAGENT 1:

EDTA-Na₂ 0.1 mmol/l

NaCl 9 g/l

Sulfamic acid 100 mmol/l

REAGENT 2:

2,4-dichlorophenyl-diazonium salt 0.5 mmol/l

HCl 700 mmol/l

EDTA-Na₂ 0.13 mmol/l

Hazardous ingredients:

(name, concentration)

Dangerous preparation according to 67/548/EEC - 88/379/EEC:

In accordance to the EC Directive 88/379/EC, this product has not to be classified as hazardous material.

3. Hazards identification

Most important hazards:

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.

Specific risks:

4. First-aid measures

Inhalation:

Skin contact:

Rinse with water.

Eye contact:

Rinse with water.

Ingestion:

Give extensive water for drinking, consult doctor if feeling unwell.

5. Fire-fighting measures

Extinguishing media:

Specific risks:

Special protective equipment:

Additional recommendations:

Product is not flammable.

6. Accidental release measures

Personal precautions:

Environmental precautions:

Methods for cleaning / absorption:

Dilute with water and absorb with liquid absorbing material. Dispose of according to local regulations. Clean affected area.

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7. Handling and storage

7.1 Handling:

Technical measures: No special requirements.

Precautions: No special requirements.

Handling recommendations: No special requirements.

7.2 Storage:

Technical measures:

Storage conditions: Store protected from light and tightly closed at +2°C - +8°C. Do not freeze the reagents.

Incompatible materials:

Packaging materials:

8. Exposure controls/personal protection

Specific control parameters:

Technical measures:

Respiratory protection: Not required.

Hand protection: Required.

Eye protection: Required.

Skin protection: Required.

Hygiene measures: Change contaminated cloths. Wash hands after handling the substance.

9. Physical and chemical properties

Physical state: Liquid; aqueous clear solution.

Colour: Colourless.

Odour: No characteristic odour.

pH: REAGENT 1: 1.1 (25°C)
REAGENT 2: 0.05 (25°C)

Boiling point: Not applicable.

Melting point: Not applicable.

Flashing point: Not applicable.

Flammability (solid, gas): Not applicable.

Auto-flammability: Not applicable.

Explosive properties: Not applicable.

Oxidizing properties: Not applicable.

Vapour pressure: Not applicable.

Relative density: REAGENT 1: 1.0103 g/ml (20°C)

REAGENT 2: 1.0142 g/ml (20°C)

Solubility: Not applicable.

Partition coefficient:

Other data:

10. Stability and reactivity

Conditions to avoid: None known.

Materials to avoid: None known.

Hazardous decomposition products: None known.

Other data:

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11. Toxicological information

| | |
|--------------------------|---|
| Acute toxicity: | Not known. |
| Chronic toxicity: | Not known. |
| Inhalation: | Not known. |
| Skin contact: | Not known. |
| Eye contact: | Not known. |
| Ingestion: | Not known. |
| Other data: | Quantitative data about the toxicity of the product are not available. Dangerous properties cannot be ruled out. However, risks are not to be expected, if the product is handled by qualified and authorized personnel with the necessary precautions for chemicals/ diagnostic reagents. |

12. Ecological information

| | |
|-----------------------------------|---|
| Mobility: | |
| Degradability: | |
| Bioaccumulative potential: | |
| Ecotoxicity: | Risk of water pollution: Class 1 according to German Federal regulation. |
| Other hazardous effects: | Quantitative data on ecological effects of the product are not available. |

13. Disposal considerations

| | |
|-------------------------------------|---|
| Surplus or waste (residues): | There are no common EC regulations for the disposal of chemicals or residues yet. Chemical residues are generally considered as special waste. The disposal of the latter is regulated in the EC member countries through respective laws and regulations. We recommend that you contact either authorities in charge or approved waste disposal companies which will advise you on how to dispose of special waste. |
| Contaminated packaging: | Disposal in accordance with local legal provisions. |

14. Transport information (International regulations)

| | |
|-----------------------------|--|
| By land: | N/A. |
| By river: | N/A. |
| By air: | REAGENT 1: not subject to current regulations for transportation of hazardous goods (IMDG, IATA/ICAO). REAGENT 2: subject to current regulations for transportation of hazardous goods (IMDG, IATA/ICAO). <ul style="list-style-type: none">• Proper shipping name: Corrosive liquid, basic, inorganic, n.o.s (bilirubin direct).• UN-Number: UN 3264 (Excepted Quantities).• Hazard Class and packaging group: 8, III.• label(s): Corrosive.• Packing instruction (passenger aircraft): IATA 818 (5).• Unit volume: 6 ml.• Sales unit: 1 bottle/ kit. |
| By sea: | N/A. |
| General information: | N/A. |

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15. Regulatory information

Labelling according to EEC directives:

Symbols: Corrosive.

R phrases: N/A.

S phrases: N/A.

Substances: N/A.

Other regulatory requirements: In accordance to the EC Directive 88/379/EC, this product has not to be classified as hazardous material.

16. Other information

This product is intended for IN VITRO diagnostic use only.

NOT FOR USE IN HUMANS.

The information given herein is based on the present state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not a guarantee properties of the product.