HORIBA Medical

Material Safety Data Sheet

ABX Pentra Bilirubin Total CP	A91A00560DEN	20/05/2010

1. Product and company identification

1.1. Identification of the product

Product name:	ABX Pentra Bilirubin Total CP
Product code:	Ref.HORIBA Medical: A11A01639

1.2. Use of the product

Diagnostic reagent for quantitative in-vitro determination of total Bilirubin in serum and plasma of adults and neonates.

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): Yes

Most important hazards:	REAGENT 1 : R 52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Specific risks	A corrosive effect cannot be ruled out because of the pH value (R1= 0.8; R2= 0.9).

3. Composition/information on ingredients

3.1. Description of the kit

	REAGENT : Bi-reagent cassette REAGENT 1 : 1 x 29.5 ml REAGENT 2 : 1 x 9.8 ml

FORM-0307-A, revision 7

3.2. Hazardous ingredients (name, concentration)

CAS N.	EC N.	Name	Concentration	Symbol	Risk	Registration number
		REAGENT 1 :				
57-09-0	200-311-3 (EINECS)	Cetrimonium bromide	1-2 %	Xn, N	R22, R36/37/38, R50/53	
7647-01-0	231-595-7 (EINECS)	Hydrochloric acid, aqueous solution	1-5 %	C	R34	
9002-93-1	-	Octylphenoxypoly-ethoxyethanol	≤ 1 %	Xn, N	R22, R41, R51/53	
9002-92-0	500-002-6 (NLP)	Dodecan-1-ol, ethoxylated	≤ 1 %	Xn, N	R22, R41, R50	
		REAGENT 2 :				
9002-92-0	500-002-6 (NLP)	Dodecan-1-ol, ethoxylated	1 % ≤ c < 5%	Xn, N	R22, R41, R50	
7647-01-0	231-595-7 (EINECS)	Hydrochloric acid, aqueous solution	≤ 1 %	C	R34	

4. First-aid-measures

Inhalation:	Provide fresh air. Seek medical aid in case of troubles.
Skin contact:	Remove immediately all contaminated clothing. In case of contact, immediately flush skin with copious amounts of cool water. Cover with sterile dressing material to protect against infection. Seek medical attention.
Eye contact:	Immediately wash eyes, also under the eyelids, with water for at least 15 minutes. Subsequently seek the immediate attention of an ophthalmologist.
Ingestion:	Rinse mouth immediately and drink large quantities of water. Do not induce vomiting. Risk of peforation! Do not try to neutralize. Seek medical attention.

5. Fire-fighting measures : Product non flammable

Extinguishing media:	Use whatever is required for the surrounding area.
Specific risks:	REAGENT 1 : Fires in the immediate vicinity may cause the development of dangerous vapors. Can be released in case of fire: hydrochloric, bromide hydrogen (HBr), nitrogen oxides (NOx), carbon monoxide and carbon dioxide. REAGENT 2 : Fires in the immediate vicinity may cause the development of dangerous vapors. Can be released in case of fire: hydrochloric, nitrogen oxides (NOx), carbon monoxide and carbon dioxide.
Special protective equipment:	Wear self-contained breathing apparatus.
Additional recommendations:	Do not allow fire water to penetrate into surface or ground water.

6. Accidental release measures

Personal precautions:	Wear a lab coat, protective gloves and safety goggles. Avoid contact with skin and eyes.

Environmental precautions:	Prevent from getting into soil, waterbodies or drains.
Methods for cleaning/absorption:	Soak up with absorbent materials such as sand, siliceus earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance. Final cleaning.

7. Handling and storage

7.1. Handling

Technical measures:	Provide adequate ventilation, and local exhaust as needed.
Precautions:	The usual laboratory precautions should be observed.
Handling recommendations:	Avoid contact with skin and eyes.

7.2. Storage

Technical measures:	No special requirements.
Storage conditions:	Store protected from light, in tightly closed containers, under a cool condition (2-8°C). Do not freeze the reagents. Keep sterile.
Incompatible materials:	Metals.
Packaging materials:	No special requirements.

8. Exposure controls/personal protection

8.1. Exposure limit values

CAS N.	Chemical name	Type	Value
7647-01-0	Hydrochloric acid, aqueous solution	WEL-TWA WEL-TWA WEL-STEL WEL-STEL Indicative Occupational Exposure Limit Value Europe Indicative Occupational Exposure Limit Value Europe Indicative Occupational Exposure Limit Value Europe, short term Indicative Occupational Exposure Limit Value Europe, short term	(gas aerosol mists) 1 ppm (gas aerosol mists) 2 mg/m^3 (gas aerosol mists) 5 ppm (gas aerosol mists) 8 mg/m^3 (Hydrogen chloride) 5 ppm (Hydrogen chloride) 8 mg/m^3 (Hydrogen chloride) 10 ppm (Hydrogen chloride) 15 mg/m^3

8.2. Exposure controls

8.2.1. Occupational exposure controls

Technical measures:	Use general room ventilation.
Respiratory protection:	Respiratory protection must be worn whenever the WEL levels have been exceeded. Combination filter (E-P2/P3) according to EN 141.
Hand protection:	Protective gloves according to EN 374. Glove material: Nitril ruber-Layer thickness: 0.11 mm. Breakthrough time: >480 min. Observe glove manufacturer's instructions concerning penetrability and breakthrough time.
Eye protection:	Tightly sealed safety glasses according to EN 166.

Skin protection:	Lab coat.
Hygiene measures:	Change contaminated clothes. Wash hands before breaks and at the end of the work. Provide a conveniently located rinse station.

8.2.2. Environmental exposure controls

Not available.	

9. Physical and chemical properties

9.1. General information

Physical state:	REAGENT 1 : Liquid REAGENT 2 : Liquid		
Colour:	REAGENT 1 : Colourless, clear REAGENT 2 : Yellow up to reddish, clear	Odour:	REAGENT 1 : Odourless REAGENT 2 : Odourless

9.2. Important health, safety and environmental information

pH:	REAGENT 1 : 0.75-0.85 (25°C) REAGENT 2 : 0.90-0.95 (25°C)	Relative density:	REAGENT 1 : 1.0124 g/ml (20°C) REAGENT 2 : 1.001 g/ml (20°C)
Boiling point:	Not available	Solubility in water:	REAGENT 1 : Fully miscible (20°C) REAGENT 2 : Fully miscible (20°C)
Flash point:	Not combustible	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

10. Stability and reactivity

Conditions to avoid:	None known.
Materials to avoid:	Alkalis.
Hazardous decomposition products:	REAGENT 1 : Can be released in case of fire: hydrochloric, bromide hydrogen (HBr), nitrogen oxides (NOx), carbon monoxide and carbon dioxide. REAGENT 2 : Can be released in case of fire: hydrochloric, nitrogen oxides (NOx), carbon monoxide and carbon dioxide.
Other data:	No hazardous reactions known when used appropriately.

11. Toxicological information

Acute toxicity:	Not determined.
Chronic toxicity:	Not determined.
Inhalation:	Not determined.

Skin contact:	A corrosive effect cannot be ruled out because of the pH value.
Eye contact:	A corrosive effect cannot be ruled out because of the pH value. Risk of serious damage to eyes.
Ingestion:	Burns.
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

12.1. Ecotoxicity:	REAGENT 1 : Aquatoxicity: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Harmful effects on water organisms by modification of pH-value. Water hazard class: 2 = water pollutant REAGENT 2 : Aquatoxicity: Harmful effects on water organisms by modification of pH-value. Water hazard class: 1 = mild water pollutant
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:	REAGENT 1 : Contains non-ionic surfactants (Dodecan-1-ol, ethoxylated) and cationic surfactants (Centrimonium bromide). Do not allow to enter ground water, sewage or drains. REAGENT 2 : Contains non-ionic surfactants (Dodecan-1-ol, ethoxylated). Do not allow to enter ground water, sewage or drains.

13. Disposal considerations

Surplus or waste (residues) Contaminated packaging	It is advisable to avoid or reduce the generation of waste products whenever possible. Empty containers may contain product residues. Discard all waste, unsused 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.

14. Transport information (International regulations)

General information:	REAGENT 1 : Appropriate shipping name: UN number: Risk category: Label(s): Unit volume: Sales unit: REAGENT 2 : Appropriate shipping name: UN number: Risk category: Label(s): Unit volume: Sales unit:	 Corrosive liquid, acidic, inorganic, n.o.s. (HCl). UN3264 (Excepted quantities) 8 Corrosive 29.5 ml 1 bottle/kit Corrosive liquid, acidic, inorganic, n.o.s. (HCl). UN3264 (Excepted quantities) 8 Corrosive 9.8 ml 1 bottle/kit
By air (IATA):	REAGENT 1 : Packaging group: Packaging instructions (passenger aircraft):	 III 818 (5L)
By land (European ADR):	Appropriate shipping name: UN number Risk category: Packing group: Limited quantities:	Corrosive liquid, acidic, inorganic, n.o.s. (HCl). UN3264 (Excepted quantities) 8 III LQ7
By sea (IMDG):	Appropriate shipping name: UN number Risk category: Packing group: Limited quantities:	Corrosive liquid, acidic, inorganic, n.o.s. (HCl). UN3264 (Excepted quantities) 8 III 5L

15. Regulatory information

Symbols:	None	
R phrases:	REAGENT 1 : R 52/53 REAGENT 2 : None	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
S phrases:	REAGENT 1 : S 24/25 S 61 REAGENT 2 : S24/25	Avoid contact with skin and eyes. Avoid release to the environment. Refer to special instructions/Safety data sheets. Avoid contact with skin and eyes.
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

R 22	Harmful if swallowed.
R 34	Causes burns.
R 36/37/38	Irritating to eyes, respiratory system and skin.
R 41	Risk of serious damage to eyes.
R 50	Very toxic to aquatic organisms.
R 50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R 51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R 52/53	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

16.2. Recommended restriction on use

See specific information 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 base 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.