

## SECTION 1: Identification of the substance/mixture and of the company/ undertaking

### 1.1 Product identifier

**Product name** : ABX Pentra Bilirubin Direct CP - R1 // Yumizen C1200 Direct Bilirubin - R1  
**SAP Code** : 1220001635 // 1300023834  
**Product is part of kit** : A11A01635 // 1300023834  
**Product description** : 24 mL // 6 X 16 mL  
**Product type** : Liquid.  
**Other means of identification** : Not available.

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

#### Identified uses

Diagnostic reagent for quantitative *in vitro* determination of Direct Bilirubin in serum or plasma by colorimetry.

#### Uses advised against

Not applicable.

### 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

#### National contact

HORIBA UK Ltd  
Kyoto Close  
Northampton  
NN3 6FL  
Tel: +44 (0) 1604 542500  
e-mail: sds.huk@horiba.com

### 1.4 Emergency telephone number

#### National advisory body/Poison Centre

**Telephone number** : 0344 892 0111 (Healthcare Professionals)  
111 (Members of the public)

#### 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 UK CLP/GHS

Met. Corr. 1, H290

The product is classified as hazardous according to UK CLP Regulation SI 2019/720 as amended.

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

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

### 2.2 Label elements

**Hazard pictograms** :



**Signal word** : Warning

**Hazard statements** : May be corrosive to metals.

#### Precautionary statements

**Prevention** : Keep only in original packaging.

**Response** : Absorb spillage to prevent material damage.

**Storage** : Store in corrosive resistant container with a resistant inner liner.

**Disposal** : Not applicable.

**Supplemental label elements** : Not applicable.

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

#### Special packaging requirements

**Containers to be fitted with child-resistant fastenings** : Not applicable.

**Tactile warning of danger** : Not applicable.

### 2.3 Other hazards

**Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII** : This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

**Other hazards which do not result in classification** : None known.

## SECTION 3: Composition/information on ingredients

**3.2 Mixtures** : Mixture

### SECTION 3: Composition/information on ingredients

Product/ingredient name	Identifiers	%	Classification	Type
sulphamidic acid	EC: 226-218-8 CAS: 5329-14-6 Index: 016-026-00-0	≤1	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Aquatic Chronic 3, H412  <b>See Section 16 for the full text of the H statements declared above.</b>	[1]

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, vPvBs or Substances of equivalent concern, 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

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. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing.
- Skin contact** : Wash contaminated skin with soap and water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
- Ingestion** : Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training.

#### 4.2 Most important symptoms and effects, both acute and delayed

##### 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

#### 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

## SECTION 5: Firefighting measures

- Hazards from the substance or mixture** : In a fire or if heated, a pressure increase will occur and the container may burst.
- Hazardous combustion 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.
- 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.

## 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. 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 the information in "For non-emergency personnel".

### 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).

### 6.3 Methods and material for containment and cleaning up

- Small spill** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Absorb spillage to prevent material damage. Dispose of via a licensed waste disposal contractor.
- Large spill** : Stop leak if without risk. Move containers from spill area. Absorb spillage to prevent material damage. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). The spilled material may be neutralized with sodium carbonate, sodium bicarbonate or sodium hydroxide. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilt product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

### 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.

## 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. Avoid breathing vapour or mist. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Keep away from alkalis. Empty containers retain product residue and can be hazardous. Do not reuse container. Absorb spillage to prevent material damage.
- 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. Store in corrosive resistant container with a resistant inner liner. Separate from alkalis. Keep away from metals. 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. See Section 10 for incompatible materials before handling or use.

### 7.3 Specific end use(s)

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

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational exposure limits

No exposure limit value known.

#### Biological exposure indices

No exposure indices known.

- Recommended monitoring procedures** : Reference should be made to appropriate monitoring standards. Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

#### DNELs/DMELs

Product/ingredient name	Type	Exposure	Value	Population	Effects
sulphamidic acid	DNEL	Long term Oral	5 mg/kg bw/day	General population	Systemic
	DNEL	Long term Dermal	5 mg/kg bw/day	General population	Systemic
	DNEL	Long term Dermal	10 mg/kg bw/day	Workers	Systemic
	DNEL	Long term Inhalation	17,4 mg/m <sup>3</sup>	General population	Systemic
	DNEL	Long term Inhalation	70,5 mg/m <sup>3</sup>	Workers	Systemic

#### PNECs

No PNECs available

## SECTION 8: Exposure controls/personal protection

### 8.2 Exposure controls

**Appropriate engineering controls** : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

#### 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, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields. Recommended: Tightly sealed goggles according to EN 166.

#### 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. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated. > 8 hours (breakthrough time): Protective gloves according to EN 374.

**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** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use. Recommended: Combination filtering device according to EN 14387.

**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

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

### 9.1 Information on basic physical and chemical properties

#### Appearance

**Physical state** : Liquid. [Clear.]

**Colour** : Colourless.

**Odour** : Odourless.

**Odour threshold** : Not available.

**Melting point/freezing point** : Not available.

**Initial boiling point and boiling range** : Not available.

**Flammability** : Non-flammable.  
In a fire, decomposition may produce toxic gases/fumes.

## SECTION 9: Physical and chemical properties

<b>Upper/lower flammability or explosive limits</b>	: Not available.
<b>Flash point</b>	: Not applicable.
<b>Auto-ignition temperature</b>	: Not applicable.
<b>Decomposition temperature</b>	: Not available.
<b>pH</b>	: 0,6 to 1,6
<b>Viscosity</b>	: Not available.
<b>Solubility(ies)</b>	:

Media	Result
cold water	Easily soluble
hot water	Easily soluble

<b>Solubility in water</b>	: Not available.
<b>Partition coefficient: n-octanol/ water</b>	: Not applicable.
<b>Vapour pressure</b>	: Not available.
<b>Relative density</b>	: 1,0103
<b>Density</b>	: 1,0103 g/cm <sup>3</sup> [20°C (68°F)]
<b>Vapour density</b>	: Not available.
<b>Explosive properties</b>	: Not available.
<b>Oxidising properties</b>	: Not available.
<b>Particle characteristics</b>	
<b>Median particle size</b>	: Not applicable.

## SECTION 10: Stability and reactivity

<b>10.1 Reactivity</b>	: No specific test data related to reactivity available for this product or its ingredients.
<b>10.2 Chemical stability</b>	: The product is stable.
<b>10.3 Possibility of hazardous reactions</b>	: Under normal conditions of storage and use, hazardous reactions will not occur.
<b>10.4 Conditions to avoid</b>	: No specific data.
<b>10.5 Incompatible materials</b>	: Attacks many metals producing extremely flammable hydrogen gas which can form explosive mixtures with air. Reactive or incompatible with the following materials: alkalis metals
<b>10.6 Hazardous decomposition products</b>	: 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
sulphamidic acid	LD50 Oral	Rat	3160 mg/kg	-

**Conclusion/Summary** : Not available.

#### Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapours) (mg/l)	Inhalation (dusts and mists) (mg/l)
sulphamidic acid	3160	N/A	N/A	N/A	N/A

#### Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
sulphamidic acid	Eyes - Moderate irritant	Rabbit	-	20 mg	-
	Eyes - Severe irritant	Rabbit	-	24 hours 250 ug	-
	Skin - Mild irritant	Human	-	120 hours 4 % I	-
	Skin - Severe irritant	Rabbit	-	24 hours 500 mg	-

**Conclusion/Summary** : Not available.

#### Sensitisation

**Conclusion/Summary** : Not available.

#### Mutagenicity

**Conclusion/Summary** : Not available.

#### Carcinogenicity

**Conclusion/Summary** : Not available.

#### Reproductive toxicity

**Conclusion/Summary** : Not available.

#### Teratogenicity

**Conclusion/Summary** : Not available.

#### Specific target organ toxicity (single exposure)

Not available.

#### Specific target organ toxicity (repeated exposure)

Not available.

#### Aspiration hazard

Not available.

**Information on 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** : No known significant effects or critical hazards.

## SECTION 11: Toxicological information

### Symptoms related to the physical, chemical and toxicological characteristics

<b>Eye contact</b>	: No specific data.
<b>Inhalation</b>	: No specific data.
<b>Skin contact</b>	: No specific data.
<b>Ingestion</b>	: No specific data.

### Delayed and immediate effects as well as chronic effects from short and long-term exposure

#### Short term exposure

<b>Potential immediate effects</b>	: Not available.
<b>Potential delayed effects</b>	: Not available.

#### Long term exposure

<b>Potential immediate effects</b>	: Not available.
<b>Potential delayed effects</b>	: Not available.

#### Potential chronic health effects

Not available.

<b>Conclusion/Summary</b>	: Not available.
<b>General</b>	: No known significant effects or critical hazards.
<b>Carcinogenicity</b>	: No known significant effects or critical hazards.
<b>Mutagenicity</b>	: No known significant effects or critical hazards.
<b>Reproductive toxicity</b>	: No known significant effects or critical hazards.

**Other information** : Not available.

## SECTION 12: Ecological information

### 12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
sulphamidic acid	Acute LC50 14200 µg/l Fresh water	Fish - Fathead minnow - Pimephales promelas	96 hours

**Conclusion/Summary** : Not available.

### 12.2 Persistence and degradability

**Conclusion/Summary** : Not available.

### 12.3 Bioaccumulative potential

Product/ingredient name	LogP <sub>ow</sub>	BCF	Potential
sulphamidic acid	0,101	-	low

### 12.4 Mobility in soil

<b>Soil/water partition coefficient (K<sub>oc</sub>)</b>	: Not available.
<b>Mobility</b>	: Not available.

### 12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

## SECTION 12: Ecological information

**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. 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. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.





**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.

**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 spilled material and runoff and contact with soil, waterways, drains and sewers.

## SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
<b>14.1 UN number</b>	UN3264	UN3264	UN3264	UN3264
<b>14.2 UN proper shipping name</b>	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (sulphamidic acid)	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (sulphamidic acid)	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (sulphamidic acid)	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (sulphamidic acid)
<b>14.3 Transport hazard class(es)</b>	8 	8 	8 	8 
<b>14.4 Packing group</b>	III	III	III	III
<b>14.5 Environmental hazards</b>	No.	No.	No.	No.

### Additional information

**ADR/RID** : **Remarks** Limited quantity  
**ADN** : **Remarks** Limited quantity  
**IMDG** : **Remarks** Limited quantity  
**IATA** : **Remarks** Excepted quantities

## SECTION 14: Transport information

**14.6 Special precautions for user** : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**14.7 Transport in bulk according to IMO instruments** : Not available.

## SECTION 15: Regulatory information

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture UK (GB)/REACH**

### Annex XIV - List of substances subject to authorisation

#### Annex XIV

None of the components are listed.

#### Substances of very high concern

None of the components are listed.

#### Ozone depleting substances

Not listed.

#### Prior Informed Consent (PIC)

Not listed.

#### Persistent Organic Pollutants

Not listed.

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

#### Seveso Directive

This product is not controlled under the Seveso Directive.

#### National regulations

##### EU regulations

**Industrial emissions (integrated pollution prevention and control) - Air** : Not listed

**Industrial emissions (integrated pollution prevention and control) - Water** : Not listed

##### International regulations

#### Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

#### Montreal Protocol

Not listed.

#### Stockholm Convention on Persistent Organic Pollutants

Not listed.

## SECTION 15: Regulatory information

### Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.


### UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

### Inventory list

<b>Australia</b>	: All components are listed or exempted.
<b>Canada</b>	: All components are listed or exempted.
<b>China</b>	: All components are listed or exempted.
<b>Eurasian Economic Union</b>	: <b>Russian Federation inventory</b> : All components are listed or exempted.
<b>Japan</b>	: <b>Japan inventory (CSCL)</b> : All components are listed or exempted. <b>Japan inventory (ISHL)</b> : Not determined.
<b>New Zealand</b>	: All components are listed or exempted.
<b>Philippines</b>	: All components are listed or exempted.
<b>Republic of Korea</b>	: All components are listed or exempted.
<b>Taiwan</b>	: All components are listed or exempted.
<b>Thailand</b>	: All components are listed or exempted.
<b>Turkey</b>	: All components are listed or exempted.
<b>United States</b>	: All components are active or exempted.
<b>Viet Nam</b>	: All components are listed or exempted.
<b>15.2 Chemical safety assessment</b>	: Not applicable.

## 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
- GB CLP = UK CLP (EC No 1272/2008) on the Classification, Labelling and Packaging of Substances and Mixtures as amended by (EU Exit) Regulations 2019 No. 720 and amendments
- DMEL = Derived Minimal Effect Level
- DNEL = Derived No Effect Level
- EUH statement = GB CLP-specific Hazard statement
- N/A = Not available
- PBT = Persistent, Bioaccumulative and Toxic
- PNEC = Predicted No Effect Concentration
- RRN = REACH Registration Number
- SGG = Segregation Group
- vPvB = Very Persistent and Very Bioaccumulative

### Procedure used to derive the classification

Classification	Justification
Met. Corr. 1, H290	Expert judgment

### Full text of abbreviated H statements

H290	May be corrosive to metals.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H412	Harmful to aquatic life with long lasting effects.

### Full text of classifications

## SECTION 16: Other information

Aquatic Chronic 3	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 3
Eye Irrit. 2	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2
Met. Corr. 1	CORROSIVE TO METALS - Category 1
Skin Irrit. 2	SKIN CORROSION/IRRITATION - Category 2

**Date of printing** : 17/05/2023  
**Date of issue/ Date of revision** : 17/05/2023  
**Date of previous issue** : No previous validation  
**Version** : 5

### 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.

## SECTION 1: Identification of the substance/mixture and of the company/ undertaking

### 1.1 Product identifier

**Product name** : ABX Pentra Bilirubin Direct CP - R2 // Yumizen C1200 Direct Bilirubin - R2  
**SAP Code** : 1220001635 // 1300023834  
**Product is part of kit** : A11A01635 // 1300023834  
**Product description** : 7 mL // 6 X 6 mL  
**Product type** : Liquid.  
**Other means of identification** : Not available.

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

#### Identified uses

Diagnostic reagent for quantitative *in vitro* determination of Direct Bilirubin in serum or plasma by colorimetry.

#### Uses advised against

Not applicable.

### 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

#### National contact

HORIBA UK Ltd  
Kyoto Close  
Northampton  
NN3 6FL  
Tel: +44 (0) 1604 542500  
e-mail: sds.huk@horiba.com

### 1.4 Emergency telephone number

#### National advisory body/Poison Centre

**Telephone number** : 0344 892 0111 (Healthcare Professionals)  
111 (Members of the public)

#### 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 UK CLP/GHS

Met. Corr. 1, H290

The product is classified as hazardous according to UK CLP Regulation SI 2019/720 as amended.

**Ingredients of unknown toxicity** : 3,3 percent of the mixture consists of component(s) of unknown acute oral toxicity  
3,3 percent of the mixture consists of component(s) of unknown acute dermal toxicity  
3,3 percent of the mixture consists of component(s) of unknown acute inhalation toxicity

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

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

### 2.2 Label elements

**Hazard pictograms** :



**Signal word** : Warning

**Hazard statements** : May be corrosive to metals.

#### Precautionary statements

**Prevention** : Keep only in original packaging.

**Response** : Absorb spillage to prevent material damage.

**Storage** : Store in corrosive resistant container with a resistant inner liner.

**Disposal** : Not applicable.

**Supplemental label elements** : Not applicable.

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

#### Special packaging requirements

**Containers to be fitted with child-resistant fastenings** : Not applicable.

**Tactile warning of danger** : Not applicable.

### 2.3 Other hazards

**Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII** : This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

**Other hazards which do not result in classification** : None known.

**SECTION 3: Composition/information on ingredients****3.2 Mixtures** : Mixture

Product/ingredient name	Identifiers	%	Classification	Type
hydrochloric acid mixture	EC: 231-595-7 CAS: 7647-01-0 Index: 017-002-01-X	≤5	Met. Corr. 1, H290 Skin Corr. 1B, H314 STOT SE 3, H335  <b>See Section 16 for the full text of the H statements declared above.</b>	[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, vPvBs or Substances of equivalent concern, 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

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. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing.
- Skin contact** : Wash contaminated skin with soap and water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
- Ingestion** : Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training.

**4.2 Most important symptoms and effects, both acute and delayed**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****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** : In a fire or if heated, a pressure increase will occur and the container may burst.
- Hazardous combustion products** : Decomposition products may include the following materials:  
halogenated compounds

### 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.
- 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.

## 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. 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 the information in "For non-emergency personnel".

### 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).

### 6.3 Methods and material for containment and cleaning up

- Small spill** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Absorb spillage to prevent material damage. Dispose of via a licensed waste disposal contractor.
- Large spill** : Stop leak if without risk. Move containers from spill area. Absorb spillage to prevent material damage. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). The spilled material may be neutralized with sodium carbonate, sodium bicarbonate or sodium hydroxide. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilt product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

### 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.

## 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. Avoid breathing vapour or mist. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Keep away from alkalis. Empty containers retain product residue and can be hazardous. Do not reuse container. Absorb spillage to prevent material damage.
- 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. Store in corrosive resistant container with a resistant inner liner. Separate from alkalis. Keep away from metals. 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. See Section 10 for incompatible materials before handling or use.

### 7.3 Specific end use(s)

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

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational exposure limits

Product/ingredient name	Exposure limit values
hydrochloric acid mixture	<b>EH40/2005 WELs (United Kingdom (UK), 1/2020).</b> STEL: 8 mg/m <sup>3</sup> 15 minutes. Form: (gas and aerosol mists) STEL: 5 ppm 15 minutes. Form: (gas and aerosol mists) TWA: 2 mg/m <sup>3</sup> 8 hours. Form: (gas and aerosol mists) TWA: 1 ppm 8 hours. Form: (gas and aerosol mists)

#### Biological exposure indices

No exposure indices known.

- Recommended monitoring procedures** : Reference should be made to appropriate monitoring standards. Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

#### DNELs/DMELs

## SECTION 8: Exposure controls/personal protection

Product/ingredient name	Type	Exposure	Value	Population	Effects
hydrochloric acid mixture	DNEL	Long term Inhalation	8 mg/m <sup>3</sup>	General population	Local
	DNEL	Long term Inhalation	8 mg/m <sup>3</sup>	Workers	Local
	DNEL	Short term Inhalation	15 mg/m <sup>3</sup>	General population	Local
	DNEL	Short term Inhalation	15 mg/m <sup>3</sup>	Workers	Local

### PNECs

No PNECs available

### 8.2 Exposure controls

**Appropriate engineering controls** : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

### 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, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields. Recommended: Tightly sealed goggles according to EN 166.

### 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. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated. > 8 hours (breakthrough time): Protective gloves according to EN 374.

**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** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use. Recommended: Combination filtering device according to EN 14387.

**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

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

### 9.1 Information on basic physical and chemical properties

#### Appearance

<b>Physical state</b>	: Liquid. [Clear.]
<b>Colour</b>	: Colourless.
<b>Odour</b>	: Odourless.
<b>Odour threshold</b>	: Not available.
<b>Melting point/freezing point</b>	: Not available.
<b>Initial boiling point and boiling range</b>	:

Ingredient name	°C	°F	Method
hydrochloric acid mixture	109,85	229,7	

<b>Flammability</b>	: Non-flammable. In a fire, decomposition may produce toxic gases/fumes.
<b>Upper/lower flammability or explosive limits</b>	: Not available.
<b>Flash point</b>	: Not applicable.
<b>Auto-ignition temperature</b>	: Not applicable.
<b>Decomposition temperature</b>	: Not available.
<b>pH</b>	: 0 to 1
<b>Viscosity</b>	: Not available.
<b>Solubility(ies)</b>	:

Media	Result
cold water	Easily soluble
hot water	Easily soluble

<b>Solubility in water</b>	: Not available.
<b>Partition coefficient: n-octanol/ water</b>	: Not applicable.
<b>Vapour pressure</b>	: Not available.
<b>Relative density</b>	: 1,0142
<b>Density</b>	: 1,0142 g/cm <sup>3</sup> [20°C (68°F)]
<b>Vapour density</b>	: Not available.
<b>Explosive properties</b>	: Not available.
<b>Oxidising properties</b>	: Not available.
<b>Particle characteristics</b>	
<b>Median particle size</b>	: Not applicable.

## SECTION 10: Stability and reactivity

<b>10.1 Reactivity</b>	: No specific test data related to reactivity available for this product or its ingredients.
<b>10.2 Chemical stability</b>	: The product is stable.
<b>10.3 Possibility of hazardous reactions</b>	: Under normal conditions of storage and use, hazardous reactions will not occur.

## SECTION 10: Stability and reactivity

**10.4 Conditions to avoid** : No specific data.

**10.5 Incompatible materials** : Attacks many metals producing extremely flammable hydrogen gas which can form explosive mixtures with air.  
Reactive or incompatible with the following materials:  
alkalis  
metals

**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

**Conclusion/Summary** : Not available.

#### Acute toxicity estimates

N/A

#### Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
hydrochloric acid mixture	Eyes - Mild irritant	Rabbit	-	0,5 minutes	-
	Skin - Mild irritant	Human	-	5 mg 24 hours 4 %	-

**Conclusion/Summary** : Not available.

#### Sensitisation

**Conclusion/Summary** : Not available.

#### Mutagenicity

**Conclusion/Summary** : Not available.

#### Carcinogenicity

**Conclusion/Summary** : Not available.

#### Reproductive toxicity

**Conclusion/Summary** : Not available.

#### Teratogenicity

**Conclusion/Summary** : Not available.

#### Specific target organ toxicity (single exposure)

Product/ingredient name	Category	Route of exposure	Target organs
hydrochloric acid mixture	Category 3	-	Respiratory tract irritation

#### Specific target organ toxicity (repeated exposure)

Not available.

#### Aspiration hazard

Not available.

**Information on likely routes of exposure** : Not available.

#### Potential acute health effects

**Eye contact** : No known significant effects or critical hazards.

## SECTION 11: Toxicological information

- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

### 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 as well as 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

Not available.

- Conclusion/Summary** : Not available.
- General** : No known significant effects or critical hazards.
- Carcinogenicity** : No known significant effects or critical hazards.
- Mutagenicity** : No known significant effects or critical hazards.
- Reproductive toxicity** : No known significant effects or critical hazards.

**Other information** : Not available.

## SECTION 12: Ecological information

### 12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
hydrochloric acid mixture	Acute LC50 240000 µg/l Marine water	Crustaceans - Green crab - Carcinus maenas - Adult	48 hours
	Acute LC50 282 ppm Fresh water	Fish - Western mosquitofish - Gambusia affinis - Adult	96 hours

**Conclusion/Summary** : Not available.

### 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<sub>oc</sub>)** : Not available.

## SECTION 12: Ecological information

**Mobility** : Not available.

### 12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

**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. 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. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.





**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.

**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 spill material and runoff and contact with soil, waterways, drains and sewers.

## SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
<b>14.1 UN number</b>	UN3264	UN3264	UN3264	UN3264
<b>14.2 UN proper shipping name</b>	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (Hydrochloric acid, mixture)	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (Hydrochloric acid, mixture)	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (Hydrochloric acid, mixture)	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (Hydrochloric acid, mixture)
<b>14.3 Transport hazard class(es)</b>	8 	8 	8 	8 
<b>14.4 Packing group</b>	III	III	III	III
<b>14.5 Environmental hazards</b>	No.	No.	No.	No.

#### Additional information

**ADR/RID** : **Remarks** Limited quantity

**ADN** : **Remarks** Limited quantity

## SECTION 14: Transport information

**IMDG** : **Remarks** Limited quantity  
**IATA** : **Remarks** Excepted quantities

**14.6 Special precautions for user** : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**14.7 Transport in bulk according to IMO instruments** : Not available.

## SECTION 15: Regulatory information

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

#### UK (GB)/REACH

##### Annex XIV - List of substances subject to authorisation

###### Annex XIV

None of the components are listed.

###### Substances of very high concern

None of the components are listed.

###### Ozone depleting substances

Not listed.

###### Prior Informed Consent (PIC)

Not listed.

###### Persistent Organic Pollutants

Not listed.

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

###### Seveso Directive

This product is not controlled under the Seveso Directive.

###### National regulations

###### EU regulations

**Industrial emissions (integrated pollution prevention and control) - Air** : Listed

**Industrial emissions (integrated pollution prevention and control) - Water** : Not listed

###### International regulations

###### Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

###### Montreal Protocol

Not listed.

## SECTION 15: Regulatory information

### Stockholm Convention on Persistent Organic Pollutants

Not listed.

### Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

### UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

### Inventory list

<b>Australia</b>	: All components are listed or exempted.
<b>Canada</b>	: All components are listed or exempted.
<b>China</b>	: All components are listed or exempted.
<b>Eurasian Economic Union</b>	: <b>Russian Federation inventory</b> : All components are listed or exempted.
<b>Japan</b>	: <b>Japan inventory (CSCL)</b> : All components are listed or exempted. <b>Japan inventory (ISHL)</b> : All components are listed or exempted.
<b>New Zealand</b>	: All components are listed or exempted.
<b>Philippines</b>	: All components are listed or exempted.
<b>Republic of Korea</b>	: All components are listed or exempted.
<b>Taiwan</b>	: All components are listed or exempted.
<b>Thailand</b>	: All components are listed or exempted.
<b>Turkey</b>	: All components are listed or exempted.
<b>United States</b>	: All components are active or exempted.
<b>Viet Nam</b>	: All components are listed or exempted.
<b>15.2 Chemical safety assessment</b>	: Not applicable.

## 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
- GB CLP = UK CLP (EC No 1272/2008) on the Classification, Labelling and Packaging of Substances and Mixtures as amended by (EU Exit) Regulations 2019 No. 720 and amendments
- DMEL = Derived Minimal Effect Level
- DNEL = Derived No Effect Level
- EUH statement = GB CLP-specific Hazard statement
- N/A = Not available
- PBT = Persistent, Bioaccumulative and Toxic
- PNEC = Predicted No Effect Concentration
- RRN = REACH Registration Number
- SGG = Segregation Group
- vPvB = Very Persistent and Very Bioaccumulative

### Procedure used to derive the classification

Classification	Justification
Met. Corr. 1, H290	Expert judgment

### Full text of abbreviated H statements

H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H335	May cause respiratory irritation.

### Full text of classifications

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## SECTION 16: Other information

Met. Corr. 1	CORROSIVE TO METALS - Category 1
Skin Corr. 1B	SKIN CORROSION/IRRITATION - Category 1B
STOT SE 3	SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE - Category 3

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### 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.