



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

1.1 Product identifier

Product name : ABX Pentra Creatinine 120 CP - R1
Product is part of kit : A11A01933
Product description : 27.5 mL
Product type : Liquid.

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

Diagnostic reagent for quantitative *in-vitro* determination of creatinine in serum or urine 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 : +44 (0)20 7771 5310
United Kingdom (UK)

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

Met. Corr. 1, H290
Skin Irrit. 2, H315
Eye Irrit. 2, H319

The product is classified as hazardous according to Regulation (EC) 1272/2008 as amended.

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

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

Classification : Xi; R36/38

Human health hazards : Irritating to eyes and skin.

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

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SECTION 2: Hazards identification

Hazard pictograms :



Signal word : Warning

Hazard statements : **H314** May be corrosive to metals.
 Causes serious eye irritation.
 Causes skin irritation.

Precautionary statements

Prevention : **P273** Wear protective gloves/protective clothing/eye protection/face protection. Wash hands thoroughly after handling. Keep only in original container.

Response : **P301+P312** IF ON SKIN: Wash with plenty of soap and water. Specific treatment (see First Aid on this label). If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. **P303+P361+P353** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Absorb spillage to prevent material damage.

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

Disposal : Not applicable.

Hazardous ingredients : Sodium hydroxide

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.

2.3 Other hazards

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

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 hydroxide	EC: 215-185-5 CAS: 1310-73-2 Index: 011-002-00-6	>=0,5 - <2	C; R35 See Section 16 for the full text of the R-phrases declared above.	Skin Corr. 1A, H314 Eye Dam. 1, H318 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

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SECTION 3: Composition/information on ingredients

- [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
- [5] Substance of equivalent concern

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.
- 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. Continue to rinse for at least 10 minutes. Get medical attention. 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 if adverse health effects persist or are severe. 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** : Causes serious eye irritation.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : Causes skin irritation.
- Ingestion** : Irritating to mouth, throat and stomach.

Over-exposure signs/symptoms

- Eye contact** : Adverse symptoms may include the following:
pain or irritation
watering
redness
- Inhalation** : No specific data.
- Skin contact** : Adverse symptoms may include the following:
irritation
redness
- Ingestion** : No specific data.

SECTION 4: First aid measures

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.
 In a fire, decomposition may produce toxic gases/fumes.

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

- Hazards from the substance or mixture** : In a fire or if heated, a pressure increase will occur and the container may burst.
- 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.
- 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 spill material. Avoid breathing vapour or mist. 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 the information in "For non-emergency personnel".

6.2 Environmental precautions

- : Avoid dispersal of spill 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 materials for containment and cleaning up

SECTION 6: Accidental release measures

- 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. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilt product.
- 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 acids. 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: 18 to 26°C (64,4 to 78,8°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 acids. 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.

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. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker or exposure or environmental releases.

8.1 Control parameters

Occupational exposure limits

Product/ingredient name	Exposure limit values
sodium hydroxide	EH40/2005 WELs (United Kingdom (UK), 12/2011). STEL: 2 mg/m ³ 15 minutes.

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 monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

No DNELs/DMELs available.

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: chemical splash goggles.

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.

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.

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SECTION 8: Exposure controls/personal protection

- 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** : Liquid.
- Colour** : Clear. Colourless.
- Odour** : Not available.
- Odour threshold** : Not available.
- pH** : 13
- 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.
In a fire, decomposition may produce toxic gases/fumes.
- Upper/lower flammability or explosive limits** : Not available.
- Vapour pressure** : Not available.
- Vapour density** : Not available.
- Relative density** : 1,015 g/cm³ [20°C (68°F)]
- 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.
- 10.5 Incompatible materials** : Reactive or incompatible with the following materials:
acids
metals
- Other information** : Reactive or incompatible with the following materials: oxidizing materials.
- 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

No known significant effects or critical hazards.

Acute toxicity estimates

Not available.

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
sodium hydroxide	Eyes - Severe irritant	Monkey	-	24 hours 1 Percent	-
	Eyes - Mild irritant	Rabbit	-	400 Micrograms	-
	Eyes - Severe irritant	Rabbit	-	24 hours 50 Micrograms	-
	Eyes - Severe irritant	Rabbit	-	1 Percent	-
	Eyes - Severe irritant	Rabbit	-	0,5 minutes 1 milligrams	-
	Skin - Mild irritant	Human	-	24 hours 2 Percent	-
Skin - Severe irritant	Rabbit	-	24 hours 500 milligrams	-	

Sensitisation

Conclusion/Summary : Not available.

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

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SECTION 11: Toxicological information

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 the likely routes of exposure : Not available.

Potential acute health effects

- Eye contact** : Causes serious eye irritation.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : Causes skin irritation.
- Ingestion** : Irritating to mouth, throat and stomach.

Symptoms related to the physical, chemical and toxicological characteristics

- Eye contact** : Adverse symptoms may include the following:
pain or irritation
watering
redness
- Inhalation** : No specific data.
- Skin contact** : Adverse symptoms may include the following:
irritation
redness
- 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

- 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.
- 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.

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SECTION 11: Toxicological information

Other information : Not available.

SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
ABX Pentra Creatinine 120 CP CREA3 - R1 sodium hydroxide	EC50 4127 mg/l	Daphnia	48 hours
	LC50 12626 mg/l	Fish	96 hours
	Acute EC50 40,38 mg/l Fresh water	Crustaceans - Ceriodaphnia dubia - Neonate	48 hours
	Acute LC50 125 ppm Fresh water	Fish - Gambusia affinis - Adult	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. 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.





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

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	1824	1824	1824	1824
14.2 UN proper shipping name	SODIUM HYDROXIDE SOLUTION	SODIUM HYDROXIDE SOLUTION	SODIUM HYDROXIDE SOLUTION	SODIUM HYDROXIDE SOLUTION
14.3 Transport hazard class(es)	8 	8 	8 	8 
14.4 Packing group	III	III	III	III
14.5 Environmental hazards	No.	No.	No.	No.
Additional information	Remarks Limited quantity	Remarks Limited quantity	Remarks Limited quantity	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.

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

Annex XIV

None of the components are listed.

Substances of very high concern (SVHC)

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.

Seveso II Directive

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SECTION 15: Regulatory information

This product is not controlled under the Seveso II Directive.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol (Annexes A, B, C, E)

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Inform Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

International lists

National inventory

Australia	: All components are listed or exempted.
Canada	: All components are listed or exempted.
China	: <input checked="" type="checkbox"/> All components are listed or exempted.
Japan	: All components are listed or exempted.
Malaysia	: <input checked="" type="checkbox"/> All components are listed or exempted.
New Zealand	: <input checked="" type="checkbox"/> All components are listed or exempted.
Philippines	: <input checked="" type="checkbox"/> All components are listed or exempted.
Republic of Korea	: All components are listed or exempted.
Taiwan	: <input checked="" type="checkbox"/> All components are listed or exempted.
United States	: United States inventory (TSCA 8b) : All components are listed or exempted.

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

SECTION 16: Other information

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

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]
- DMEL = Derived Minimal Effect Level
- DNEL = Derived No Effect Level
- EUH statement = CLP-specific Hazard statement
- PBT = Persistent, Bioaccumulative and Toxic
- PNEC = Predicted No Effect Concentration
- RRN = REACH Registration Number
- vPvB = Very Persistent and Very Bioaccumulative

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

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SECTION 16: Other information

Classification	Justification
Met. Corr. 1, H290 Skin Irrit. 2, H315 Eye Irrit. 2, H319	Expert judgment Expert judgment Expert judgment

Full text of abbreviated H statements : H290
H314
H315
H318
H319
 May be corrosive to metals.
 Causes severe skin burns and eye damage.
 Causes skin irritation.
 Causes serious eye damage.
 Causes serious eye irritation.

Full text of classifications [CLP/GHS] : Eye Dam. 1, H318
Eye Irrit. 2, H319
Met. Corr. 1, H290
Skin Corr. 1A, H314
Skin Irrit. 2, H315
 SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 1
 SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2
 CORROSIVE TO METALS - Category 1
 SKIN CORROSION/IRRITATION - Category 1A
 SKIN CORROSION/IRRITATION - Category 2

Full text of abbreviated R phrases : R35- Causes severe burns.
R36/38- Irritating to eyes and skin.

Full text of classifications [DSD/DPD] : C - Corrosive
Xi - Irritant

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Version : 2

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 Creatinine 120 CP - R2
Product is part of kit : A11A01933
Product description : 8 mL
Product type : Liquid.

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

Diagnostic reagent for quantitative *in-vitro* determination of creatinine in serum or urine 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 : +44 (0)20 7771 5310
United Kingdom (UK)

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

Not classified.

The product is not classified as hazardous according to Regulation (EC) 1272/2008 as amended.

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

The product is not classified as dangerous according to Directive 1999/45/EC and its amendments.

Classification : Not classified.

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

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.

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SECTION 2: Hazards identification

- Response : Not applicable.
- Storage : Not applicable.
- 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.

2.3 Other hazards

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

SECTION 3: Composition/information on ingredients

Substance/mixture : Mixture

There are no 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.

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. Get medical attention if symptoms occur.
- 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. 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. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.
- 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

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.

Over-exposure signs/symptoms

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

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SECTION 4: First aid measures

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.
In a fire, decomposition may produce toxic gases/fumes.

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

- Hazards from the substance or mixture** : In a fire or if heated, a pressure increase will occur and the container may burst.
- 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.
- 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. Put on appropriate personal protective equipment.
- For emergency responders** : 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 materials for containment and cleaning up

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SECTION 6: Accidental release measures

- 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. Dispose of via a licensed waste disposal contractor.
- Large spill** : Stop leak if without risk. Move containers from spill area. 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. The spilled material may be neutralized with sodium carbonate, sodium bicarbonate or sodium hydroxide. 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.

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). Keep away from alkalis.
- 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: 18 to 26°C (64,4 to 78,8°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. Separate from alkalis. 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.

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. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker or exposure or environmental releases.

8.1 Control parameters

Occupational exposure limits

No exposure limit value known.

SECTION 8: Exposure controls/personal protection

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 monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

No DNELs/DMELs available.

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.

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	: Liquid.
Colour	: Clear. Yellow.
Odour	: Not available.
Odour threshold	: Not available.
pH	: 2
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. In a fire, decomposition may produce toxic gases/fumes.
Upper/lower flammability or explosive limits	: Not available.
Vapour pressure	: Not available.
Vapour density	: Not available.
Relative density	: 1,01 g/cm ³ [20°C (68°F)]
Solubility(ies)	: Not available.
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.
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
Other information	: Reactive or incompatible with the following materials: reducing materials.

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SECTION 10: Stability and reactivity

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

No known significant effects or critical hazards.

Acute toxicity estimates

Route	ATE value
<input checked="" type="checkbox"/> Oral	42553,2 mg/kg
<input type="checkbox"/> Dermal	63829,8 mg/kg
<input type="checkbox"/> Inhalation (dusts and mists)	106,4 mg/l

Irritation/Corrosion

No known significant effects or critical hazards.

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 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 : 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.

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SECTION 11: Toxicological information

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

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.
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.

SECTION 12: Ecological information

12.1 Toxicity

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_{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.

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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 : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 91/689/EEC.

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. 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	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.
Additional 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.

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

Annex XIV

None of the components are listed.

Substances of very high concern (SVHC)

None of the components are listed.

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

Other EU regulations

Europe inventory : All components are listed or exempted.

Seveso II Directive

This product is not controlled under the Seveso II Directive.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol (Annexes A, B, C, E)

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Inform Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

International lists

National inventory

Australia	: All components are listed or exempted.
Canada	: All components are listed or exempted.
China	: All components are listed or exempted.
Japan	: All components are listed or exempted.
Malaysia	: Not determined.
New Zealand	: All components are listed or exempted.
Philippines	: All components are listed or exempted.
Republic of Korea	: All components are listed or exempted.
Taiwan	: All components are listed or exempted.
United States	: United States inventory (TSCA 8b) : All components are listed or exempted.

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

SECTION 16: Other information

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

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]
 DMEL = Derived Minimal Effect Level
 DNEL = Derived No Effect Level
 EUH statement = CLP-specific Hazard statement
 PBT = Persistent, Bioaccumulative and Toxic
 PNEC = Predicted No Effect Concentration
 RRN = REACH Registration Number
 vPvB = Very Persistent and Very Bioaccumulative

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

Classification	Justification
<input checked="" type="checkbox"/> Not classified.	

Full text of abbreviated H statements : Not applicable.

Full text of classifications [CLP/GHS] : Not applicable.

Full text of abbreviated R phrases : Not applicable.

Full text of classifications [DSD/DPD] : Not applicable.

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Notice to reader

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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.