

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

1.1 Product identifier

Product name	: ABX Pentra Creatinine 120 CP - R1 // Yumizen C Creatinine Jaffé - R1 // Yumizen C560 Creatinine Jaffé - R1
SAP Code	: 1220001933 // 1300141429 // 1300141440
Product is part of kit	: A11A01933 // 1300141429 // 1300141440
Product description	: 30 mL // 2 X 25 mL // 4 X 29 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 creatinine in serum or urine 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

1.4 Emergency telephone number

National advisory body/Poison Centre

Telephone number : +353 1 837 9964

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.

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

Date of issue/Date of revision : 04/06/2025

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SECTION 2: Hazards identification

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.
Causes skin irritation.
Causes serious eye irritation.

Precautionary statements

Prevention :

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

Response :

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

Storage :

Store in corrosive resistant container with a resistant inner liner.

Disposal :

Not applicable.

Hazardous ingredients :

Poly(oxy-1,2-ethanediyl), α -[(1,1,3,3-tetramethylbutyl)phenyl]- ω -hydroxy-

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 :

May cause endocrine disruption.

SECTION 3: Composition/information on ingredients

3.2 Mixtures : Mixture

Product/ingredient name	Identifiers	%	Classification	Specific Conc. Limits, M-factors and ATEs	Type
sodium hydroxide	EC: 215-185-5 CAS: 1310-73-2 Index: 011-002-00-6	≤1	Skin Corr. 1A, H314 Eye Dam. 1, H318	Skin Corr. 1A, H314: C ≥ 5% Skin Corr. 1B, H314: 2% ≤ C < 5% Skin Irrit. 2, H315: 0,5% ≤ C < 2% Eye Dam. 1, H318: C ≥ 2% Eye Irrit. 2, H319: 0,5% ≤ C < 2%	[1] [2]
Poly(oxy-1,2-ethanediyl), α-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxy-	CAS: 9036-19-5	≤1	Eye Irrit. 2, H319 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 See Section 16 for the full text of the H statements declared above.	M [Acute] = 1 M [Chronic] = 1	[1] [3]

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
 [3] 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. 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

SECTION 4: First aid measures

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

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.

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

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. 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 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. 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

SECTION 7: Handling and storage

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 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

The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

8.1 Control parameters

Occupational exposure limits

Product/ingredient name	Exposure limit values
sodium hydroxide	NAOSH (Ireland, 5/2021). Notes: Advisory Occupational Exposure Limit Values (OELVs) OELV: 2 mg/m ³ 15 minutes.

Biological exposure indices

No exposure indices known.

Recommended monitoring procedures : 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

Product/ingredient name	Type	Exposure	Value	Population	Effects
sodium hydroxide	DNEL	Long term Inhalation	1 mg/m ³	General population	Local
	DNEL	Long term Inhalation	1 mg/m ³	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

SECTION 8: Exposure controls/personal protection

- 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. 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.
- Colour** : Clear. Colourless.
- Odour** : Not available.
- 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.
- Lower and upper explosion limit** : Not available.
- Flash point** : Not applicable.
- Auto-ignition temperature** : Not applicable.

SECTION 9: Physical and chemical properties

Decomposition temperature	: Not available.
pH	: 12,5 to 13,5
Viscosity	: Not available.
Solubility in water	: Not available.
Miscible with water	: Yes.
Partition coefficient: n-octanol/ water	: Not applicable.
Vapour pressure	: Not available.
Relative density	: 1,015
Density	: 1,015 g/cm ³ [20°C (68°F)]
Vapour density	: Not available.
Explosive properties	: Not available.
Oxidising properties	: Not available.
Particle characteristics	
Median particle size	: Not applicable.

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: oxidising 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 hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Poly(oxy-1,2-ethanediyl), α-[(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxy-	LD50 Oral	Rat	4190 mg/kg	-

Conclusion/Summary : Not available.

Acute toxicity estimates

SECTION 11: Toxicological information

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapours) (mg/l)	Inhalation (dusts and mists) (mg/l)
Poly(oxy-1,2-ethanediyl), α-[(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxy-	4190	N/A	N/A	N/A	N/A

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
sodium hydroxide	Eyes - Mild irritant	Rabbit	-	400 ug	-
	Eyes - Severe irritant	Monkey	-	24 hours 1 %	-
	Eyes - Severe irritant	Rabbit	-	1 %	-
	Eyes - Severe irritant	Rabbit	-	0,5 minutes	-
	Eyes - Severe irritant	Rabbit	-	1 mg	-
	Eyes - Severe irritant	Rabbit	-	24 hours 50 ug	-
Poly(oxy-1,2-ethanediyl), α-[(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxy-	Skin - Mild irritant	Human	-	24 hours 2 %	-
	Skin - Severe irritant	Rabbit	-	24 hours 500 mg	-
	Eyes - Mild irritant	Rabbit	-	15 mg	-
	Eyes - Severe irritant	Rabbit	-	1 %	-

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** : Causes serious eye irritation.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : Causes skin irritation.
- Ingestion** : No known significant effects or critical hazards.

SECTION 11: Toxicological information

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 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.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

Not available.

11.2.2 Other information

Not available.

SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
sodium hydroxide Poly(oxy-1,2-ethanediyl), α-[(1,1,3,3-tetramethylbutyl) phenyl]-ω-hydroxy-	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
	Acute EC50 210 µg/l Fresh water	Algae - Selenastrum sp.	96 hours
	Acute LC50 10800 µg/l Marine water	Crustaceans - Pandalus montagui - Adult	48 hours
	Acute LC50 2,518 mg/l Fresh water	Daphnia - Daphnia magna	48 hours
	Acute LC50 7200 µg/l Fresh water	Fish - Oncorhynchus mykiss	96 hours

- Conclusion/Summary** : Not available.

SECTION 12: Ecological information

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

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

12.6 Endocrine disrupting properties

May cause endocrine disruption.

12.7 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 spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number or ID number	UN1824	UN1824	UN1824	UN1824
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.	Yes.	No.	No.

Additional information

ADR/RID	: Remarks Limited quantity
ADN	: The product is only regulated as an environmentally hazardous substance when transported in tank vessels. Remarks Limited quantity
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 Maritime 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

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

Annex XIV - List of substances subject to authorisation

Annex XIV

Intrinsic property	Ingredient name	Status	Reference number	Date of revision
Endocrine disrupting properties for environment	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated covering well-defined substances and UVCB substances, polymers and homologues	Listed	42	03/07/2017

Substances of very high concern

SECTION 15: Regulatory information

Intrinsic property	Ingredient name	Status	Reference number	Date of revision
Endocrine disrupting properties for environment	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated covering well-defined substances and UVCB substances, polymers and homologues	Recommended	ED/169/2012	03/07/2017

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

Other EU regulations

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

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

Ozone depleting substances (1005/2009/EU)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

Persistent Organic Pollutants

Not listed.

Seveso Directive

This product is not controlled under the Seveso Directive.

National regulations

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.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Inventory list

Australia : All components are listed or exempted.

Canada : All components are listed or exempted.

China : All components are listed or exempted.

Eurasian Economic Union : **Russian Federation inventory**: All components are listed or exempted.

SECTION 15: Regulatory information

Japan	: Japan inventory (CSCL): All components are listed or exempted. Japan inventory (ISHL): 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.
Thailand	: All components are listed or exempted.
Turkey	: Not determined.
United States	: All components are active or exempted.
Viet Nam	: All components are listed or exempted.

15.2 Chemical safety assessment : Not applicable.

SECTION 16: Other information

Revision comments : Modification of section 1: product name, product code, SAP Code

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

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

Full text of abbreviated H statements

H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Full text of classifications [CLP/GHS]

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

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SECTION 16: Other information

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Version : 7

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 // Yumizen C Creatinine Jaffé - R2 // Yumizen C560 Creatinine Jaffé - R2
SAP Code	: 1220001933 // 1300141429 // 1300141440
Product is part of kit	: A11A01933 // 1300141429 // 1300141440
Product description	: 10 mL // 2 X 8 mL // 4 X 9 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 creatinine in serum or urine 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

1.4 Emergency telephone number

National advisory body/Poison Centre

Telephone number : +353 1 837 9964

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.

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

SECTION 2: Hazards identification

2.2 Label elements

Signal word	: No signal word.
Hazard statements	: No known significant effects or critical hazards.
<u>Precautionary statements</u>	
Prevention	: Not applicable.
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.
<u>Special packaging requirements</u>	
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

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. 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.

SECTION 4: First aid measures

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

- 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. 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** : 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

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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. 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

The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

8.1 Control parameters

Occupational exposure limits
No exposure limit value known.

Biological exposure indices
No exposure indices known.

SECTION 8: Exposure controls/personal protection

Recommended monitoring procedures : 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. 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. > 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.
Colour	: Clear. Yellow.
Odour	: Not available.
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.
Lower and upper explosion limit	: Not available.
Flash point	: Not applicable.
Auto-ignition temperature	: Not applicable.
Decomposition temperature	: Not available.
pH	: 1,5 to 2,5
Viscosity	: Not available.
Solubility in water	: Not available.
Partition coefficient: n-octanol/ water	: Not applicable.
Vapour pressure	: Not available.
Relative density	: 1,01
Density	: 1,01 g/cm ³ [20°C (68°F)]
Vapour density	: Not available.
Explosive properties	: Not available.
Oxidising properties	: Not available.
<u>Particle characteristics</u>	
Median particle size	: Not applicable.

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

SECTION 10: Stability and reactivity

Other information : Reactive or incompatible with the following materials: reducing materials and 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 hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

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)
ABX Pentra Creatinine 120 CP - R2 // Yumizen C Creatinine Jaffé - R2 // Yumizen C560 Creatinine Jaffé - R2	20202,0	30303,0	N/A	N/A	50,5

Irritation/Corrosion

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.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.

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SECTION 11: Toxicological information

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.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

Not available.

11.2.2 Other information

Not available.

SECTION 12: Ecological information

12.1 Toxicity

Conclusion/Summary	: Not available.
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12.2 Persistence and degradability

Conclusion/Summary	: Not available.
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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

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

12.6 Endocrine disrupting properties

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SECTION 12: Ecological information

Not available.

12.7 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 : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

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 or ID number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.

14.6 Special precautions for user : **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 Maritime 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

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

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

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

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

Ozone depleting substances (1005/2009/EU)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

Persistent Organic Pollutants

Not listed.

Seveso Directive

This product is not controlled under the Seveso Directive.

National regulations

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.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Inventory list

Australia : All components are listed or exempted.

Canada : All components are listed or exempted.

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SECTION 15: Regulatory information

China	: All components are listed or exempted.
Eurasian Economic Union	: Russian Federation inventory : All components are listed or exempted.
Japan	: Japan inventory (CSCL) : All components are listed or exempted. Japan inventory (ISHL) : 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.
Thailand	: All components are listed or exempted.
Turkey	: Not determined.
United States	: All components are active or exempted.
Viet Nam	: All components are listed or exempted.

15.2 Chemical safety assessment : Not applicable.

SECTION 16: Other information

Revision comments : Modification of section 1: product name, product code, SAP Code and Product description

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

Not classified.

Full text of abbreviated H statements

Not applicable.

Full text of classifications [CLP/GHS]

Not applicable.

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Notice to reader

SECTION 16: Other information

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.