

URINORM XL P

Creation date	26th February 2021	Version	3.0
Revision date	02nd October 2025		

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

- 1.1. Product identifier**
Substance / mixture URINORM XL P
Number mixture
REG00060
Other mixture names
URINORM XL P
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**
Mixture's intended use
URINORM XL control urines are liquid synthetic material with concentrations in the normal (URINORM XL N) and pathological (URINORM XL P) ranges. URINORM XL control urines are designed to verify the precision and accuracy of PHAN AUTO diagnostic strips and automatic urine analyzer LAURA XL intended for in vitro diagnostics. This product is intended also for evaluation of sediment. For professional use only.
Main intended use
PC-MED-OTH Other medical devices
Secondary uses
PC-TEC-19 Reagents and laboratory chemicals
Mixture uses advised against
not available
- 1.3. Details of the supplier of the safety data sheet**
Manufacturer
Name or trade name Erba Lachema s.r.o.
Address Karásek 2219/1d , Brno, 62100
Czech Republic
Identification number (CRN) 26918846
VAT number CZ26918846
Phone +420 517 077 111
Email msds@erba.com
Web address www.erba.com
Competent person responsible for the safety data sheet
Name Erba Lachema s.r.o.
Email msds@erba.com
- 1.4. Emergency telephone number**
European emergency number: 112 112

SECTION 2: Hazards identification

- 2.1. Classification of the substance or mixture**
Classification of the mixture in accordance with Regulation (EC) No 1272/2008
The mixture is not classified as dangerous according to Regulation (EC) No 1272/2008.
- 2.2. Label elements**
Signal word
none
- 2.3. Other hazards**
The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Mixture does not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended. Does not contain any PMT or vPvM components.

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SECTION 3: Composition/information on ingredients**3.2. Mixtures****Chemical characterization**

Mixture of substances and additives specified below.

Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
Index: 017-002-00-2 CAS: 7647-01-0 EC: 231-595-7	Hydrochloric acid 35%	<1	Press. Gas, Met. Corr. 1, H290 Skin Corr. 1A, H314 Acute Tox. 3, H331 STOT SE 3, H335 Specific concentration limit: Skin Corr. 1B, H314: C ≥ 25 % STOT SE 3, H335: C ≥ 10 % Skin Irrit. 2, H315: 10 % ≤ C < 25 % Eye Irrit. 2, H319: 10 % ≤ C < 25 %	1, 2, 3
Index: 011-004-00-7 CAS: 26628-22-8 EC: 247-852-1	sodium azide	≤0.1	Acute Tox. 2, H300 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1) EUH032	3
Index: 011-002-00-6 CAS: 1310-73-2 EC: 215-185-5	sodium hydroxide	<0.1	Skin Corr. 1A, H314 Specific concentration limit: Skin Corr. 1B, H314: 2 % ≤ C < 5 % Skin Corr. 1A, H314: C ≥ 5 % Eye Irrit. 2, H319: 0.5 % ≤ C < 2 % Skin Irrit. 2, H315: 0.5 % ≤ C < 2 %	3
Index: 603-117-00-0 CAS: 67-63-0 EC: 200-661-7	isopropanol	<0.01	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336	3
Index: 007-010-00-4 CAS: 7632-00-0 EC: 231-555-9	sodium nitrite	<0.01	Ox. Sol. 3, H272 Acute Tox. 3, H301 Aquatic Acute 1, H400 (M=1)	

Notes

- 1 Note U (Table 3): When put on the market gases have to be classified as "Gases under pressure", in one of the groups compressed gas, liquefied gas, refrigerated liquefied gas or dissolved gas. The group depends on the physical state in which the gas is packaged and therefore has to be assigned case by case. The following codes are assigned:

Press. Gas (Comp.)
Press. Gas (Liq.)
Press. Gas (Ref. Liq.)
Press. Gas (Diss.)

Aerosols shall not be classified as gases under pressure (See Annex I, Part 2, Section 2.3.2.1, Note 2).

- 2 Note 5: The concentration limits for gaseous mixtures are expressed as volume per volume percentage.
3 A substance for which exposure limits are set.

Full text of all classifications and hazard statements is given in the section 16.

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SECTION 4: First aid measures**4.1. Description of first aid measures**

Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet.

If inhaled

Terminate the exposure immediately; move the affected person to fresh air. Seek medical attention if breathing difficulty occurs.

If on skin

Remove contaminated clothes. Seek medical attention if symptoms of skin irritation appear.

If in eyes

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person.

If swallowed

Rinse out the mouth with clean water. In the event of issues, find medical help.

4.2. Most important symptoms and effects, both acute and delayed**If inhaled**

Not expected.

If on skin

Not expected.

If in eyes

Not expected.

If swallowed

Not expected.

4.3. Indication of any immediate medical attention and special treatment needed

Symptomatic treatment.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Accommodate extinguishing components to the location of fire.

Unsuitable extinguishing media

not available

5.2. Special hazards arising from the substance or mixture

Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

5.3. Advice for firefighters

Self-Contained Breathing Apparatus (SCBA) with chemical resistant gloves. Use a self-contained breathing apparatus and full-body protective clothing.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Follow the instructions in the Sections 7 and 8. Ensure adequate ventilation. Handle as potentially infectious.

6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water.

6.3. Methods and material for containment and cleaning up

Wipe up with adsorbent material. Place in suitable container for prompt disposal. Label the container as to the potential infectious hazard. Spill areas can be decontaminated with 0.5% sodium hypochlorite, e.g., a fresh 1:10 dilution of common household bleach.

6.4. Reference to other sections

See the Section 7, 8 and 13.

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SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Prevent formation of gases and vapours in concentrations exceeding the occupational exposure limits. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection. Wear protective safety glasses, gloves and clothing.

Wear disposable gloves while handling reagent. Thoroughly wash hands afterwards.

7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed containers in cold, dry and well ventilated areas designated for this purpose.

Storage temperature min 2 °C, max 8 °C

7.3. Specific end use(s)

For in vitro diagnostic devices.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

The mixture contains substances for which occupational exposure limits are set.

Czech Republic**Government Regulation 20/2025 Coll.**

Substance name (component)	Type	Value
Hydrochloric acid 35% (CAS: 7647-01-0)	PEL	8 mg/m ³
	PEL	5 ppm
	NPK-P	15 mg/m ³
	NPK-P	10 ppm
sodium hydroxide (CAS: 1310-73-2)	PEL	1 mg/m ³
	NPK-P	2 mg/m ³
isopropanol (CAS: 67-63-0)	PEL	500 mg/m ³
	PEL	200 ppm
	NPK-P	1000 mg/m ³
	NPK-P	400 ppm

Notes

Irritating to mucous membranes (eyes, respiratory system) and skin.

Czech Republic**Government Regulation 20/2025 Coll.**

Substance name (component)	Type	Value
sodium azide (CAS: 26628-22-8)	PEL	0,1 mg/m ³
	NPK-P	0,3 mg/m ³

Notes

Skin penetration is significantly involved during exposure.

Irritating to mucous membranes (eyes, respiratory system) and skin.

European Union**Commission Directive 2000/39/EC**

Substance name (component)	Type	Value
Hydrochloric acid 35% (CAS: 7647-01-0)	OEL 8 hours	8 mg/m ³
	OEL 8 hours	5 ppm
	OEL 15 minutes	15 mg/m ³
	OEL 15 minutes	10 ppm

European Union**Commission Directive 2000/39/EC**

Substance name (component)	Type	Value
sodium azide (CAS: 26628-22-8)	OEL 8 hours	0,1 mg/m ³
	OEL 15 minutes	0,3 mg/m ³

Notes

Skin.

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8.2. Exposure controls

Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

Eye/face protection

Wear Safety Glasses

Skin protection

Wear disposable gloves. Thoroughly wash hands.

Respiratory protection

Not required with adequate ventilation.

Thermal hazard

Not available.

Environmental exposure controls

Observe usual measures for protection of the environment, see Section 6.2.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	liquid
Colour	Straw colored
Odour	Mild odor
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available
Flammability	The product is non-flammable.
Lower and upper explosion limit	data not available
Flash point	data not available
Auto-ignition temperature	data not available
Decomposition temperature	data not available
pH	data not available
Kinematic viscosity	data not available
Solubility in water	data not available
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	data not available
Relative vapour density	data not available
Particle characteristics	data not available

9.2. Other information

not available

SECTION 10: Stability and reactivity**10.1. Reactivity**

not available

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Unknown.

10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost.

10.5. Incompatible materials

Protect against strong acids, bases and oxidizing agents.

10.6. Hazardous decomposition products

Not developed under normal uses.

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SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

No toxicological data is available for the mixture.

Acute toxicity

Based on available data the classification criteria are not met.

sodium azide					
Route of exposure	Parameter	Value	Exposure time	Species	Sex
Oral	LD ₅₀	27 mg/kg bw			
Inhalation	LC ₅₀	54 mg/m ³	4 hours	Rat	

Skin corrosion/irritation

Based on available data the classification criteria are not met.

Serious eye damage/irritation

Based on available data the classification criteria are not met.

Respiratory or skin sensitisation

Based on available data the classification criteria are not met.

Germ cell mutagenicity

Based on available data the classification criteria are not met.

Carcinogenicity

Based on available data the classification criteria are not met.

Reproductive toxicity

Based on available data the classification criteria are not met.

Toxicity for specific target organ - single exposure

Based on available data the classification criteria are not met.

Toxicity for specific target organ - repeated exposure

Based on available data the classification criteria are not met.

Aspiration hazard

Based on available data the classification criteria are not met.

11.2. Information on other hazards**Endocrine disrupting properties**

Based on the available data, the criteria for classification of the mixture are not met. Does not contain any components that may cause endocrine disruption for humans.

Other information

not available

SECTION 12: Ecological information**12.1. Toxicity**

not available

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Acute toxicity

Hydrochloric acid 35%				
Parameter	Value	Exposure time	Species	Environment
LC ₅₀	20.5 mg/l	96 hours	Fish	

sodium azide				
Parameter	Value	Exposure time	Species	Environment
LC ₅₀	680 µg/l		Fish	Fresh water
EC ₅₀ /LC ₅₀	400 µg/l		Invertebrates	Fresh water
EC ₅₀ /LC ₅₀	150 µg/l		Invertebrates	Salt water
EC ₅₀ /LC ₅₀	348 µg/l		Algae	Fresh water
EC ₅₀ /LC ₅₀	5.6 mg/l		Microorganisms	
NOEC	30 µg/l		Microorganisms	

12.2. Persistence and degradability

not available

12.3. Bioaccumulative potential

Not available.

12.4. Mobility in soil

Not available.

12.5. Results of PBT and vPvB assessment

Based on the available data, the criteria for classification of the mixture are not met. Does not contain any PBT or vPvB components. Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

12.6. Endocrine disrupting properties

Based on the available data, the criteria for classification of the mixture are not met. Does not contain any components that may cause endocrine disruption in the environment.

12.7. Other adverse effects

not available

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

Waste management legislation

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

SECTION 14: Transport information**14.1. UN number or ID number**

not subject to transport regulations

14.2. UN proper shipping name

not relevant

14.3. Transport hazard class(es)

not relevant

14.4. Packing group

not relevant

14.5. Environmental hazards

not relevant

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14.6. Special precautions for user

Reference in the Sections 4 to 8.

14.7. Maritime transport in bulk according to IMO instruments

not relevant

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16th December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006, as amended. Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

National regulations (Germany)

WGK Water hazard class: WGK 1 - slightly hazardous to water

15.2. Chemical safety assessment

not available

SECTION 16: Other information**A list of standard risk phrases used in the safety data sheet**

EUH032	Contact with acids liberates very toxic gas.
H225	Highly flammable liquid and vapour.
H272	May intensify fire; oxidiser.
H290	May be corrosive to metals.
H300	Fatal if swallowed.
H301	Toxic if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Other important information about human health protection

The product must not be - unless specifically approved by the manufacturer/importer - used for purposes other than as per the Section 1. The user is responsible for adherence to all related health protection regulations.

Key to abbreviations and acronyms used in the safety data sheet

Acute Tox.	Acute toxicity
ADR	Agreement concerning the international carriage of dangerous goods by road
Aquatic Acute	Hazardous to the aquatic environment
Aquatic Chronic	Hazardous to the aquatic environment (chronic)
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures
EC	Identification code for each substance listed in EINECS
EINECS	European Inventory of Existing Commercial Chemical Substances
EmS	Emergency Response Procedures for Ships Carrying Dangerous Goods
EU	European Union

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EuPCS	European Product Categorisation System
Eye Irrit.	Eye irritation
Flam. Liq.	Flammable liquid
IATA	International Air Transport Association
IBC	International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
INCI	International Nomenclature of Cosmetic Ingredients
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC ₅₀	Lethal concentration of a substance in which it can be expected death of 50% of the population
LD ₅₀	Lethal dose of a substance in which it can be expected death of 50% of the population
log Kow	Octanol-water partition coefficient
Met. Corr.	Corrosive to metals
NOEC	No observed effect concentration
NPK	Maximum admissible concentration
OEL	Occupational Exposure Limits
Ox. Sol.	Oxidising solid
PBT	Persistent, bioaccumulative and toxic
PEL	Permissible Exposure Limit
PMT	Persistent, mobile and toxic
ppm	Parts per million
Press. Gas (Comp.)	Gas under pressure: compressed gas
Press. Gas (Diss.)	Gas under pressure: dissolved gas
Press. Gas (Liq.)	Gas under pressure: liquefied gas
Press. Gas (Ref. Liq.)	Gas under pressure: refrigerated liquefied gas
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Regulation concerning the International Carriage of Dangerous Goods by Rail
Skin Corr.	Skin corrosion
Skin Irrit.	Skin irritation
STOT SE	Specific target organ toxicity - single exposure
UN number	Four-figure identification number of the substance or article taken from the UN Model Regulations
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials
VOC	Volatile organic compounds
vPvB	Very persistent and very bioaccumulative
vPvM	Very persistent and very mobile

Training guidelines

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

Recommended restrictions of use

not available

Information about data sources used to compile the Safety Data Sheet

REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended.
REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

The changes (which information has been added, deleted or modified)

The version 3.0 replaces the SDS version from Tuesday, 21 May 2024. Changes were made in sections 2, 11, 12, 13 and 16.

More information

Classification procedure - calculation method.

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Statement

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.