

## URINORM P

Creation date	01st March 2016	Version	4.0
Revision date	24th July 2023		

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

URINORM P

Substance / mixture

mixture

Number

REG00053

Other mixture names

URINORM

**1.2. Relevant identified uses of the substance or mixture and uses advised against****Mixture's intended use**

Urinorm P is a part of URINORM Control Urines, a liquid synthetic material with concentration within the pathological range. The kit is designed for verification and confirmation of precision and accuracy of urine analysers.

**Main intended use**

PC-MED-OTH

Other medical devices

**Secondary uses**

PC-TEC-19

Reagents and laboratory chemicals

**The use descriptors**

PC 21

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

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www.erbalachema.com

**Competent person responsible for the safety data sheet**

Name

Erba Lachema s.r.o.

E-mail

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.

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

**2.2. Label elements**

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.

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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
CAS: 10028-24-7 EC: 600-053-5	Phosphoric acid, disodium salt, dihydrate	1,63	Eye Irrit. 2, H319	
Index: 603-002-00-5 CAS: 64-17-5 EC: 200-578-6	ethanol	0,8814	Flam. Liq. 2, H225 Eye Irrit. 2, H319	1
Index: 011-002-00-6 CAS: 1310-73-2 EC: 215-185-5	sodium hydroxide	<0,2	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 %	1
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	1
Index: 603-001-00-X CAS: 67-56-1 EC: 200-659-6 Registration number: 01-2119433307-44-X	methanol	0,04639	Flam. Liq. 2, H225 Acute Tox. 3, H301+H311+H331 STOT SE 1 (**), H370 Specific concentration limit: STOT SE 1, H370: C ≥ 10 % STOT SE 2, H371: 3 % ≤ C < 10 %	1, 2, 3

## Notes

\*\* another exposure route cannot be ruled out

1 A substance for which exposure limits are set.

2 Substance for which biological limit values exist.

3 The use of the substance is restricted by Annex XVII of REACH Regulation

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

## 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.

**If on skin**

Remove contaminated clothes. After contact with skin, wash immediately with soap and water.

**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.

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**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**

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

**5.3. Advice for firefighters**

No special advice.

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

Follow the instructions in the Sections 7 and 8.

**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**

After removal of the product, wash the contaminated site with plenty of water.

**6.4. Reference to other sections**

See the Section 7, 8 and 13.

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

Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection.

**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 195/2021 Coll.**

Substance name (component)	Type	Value	Conversion for ppm	Note
ethanol (CAS: 64-17-5)	PEL	1000 mg/m <sup>3</sup>	0,522	

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## Czech Republic

## Government Regulation 195/2021 Coll.

Substance name (component)	Type	Value	Conversion for ppm	Note
ethanol (CAS: 64-17-5)	NPK-P	3000 mg/m <sup>3</sup>	0,522	
sodium hydroxide (CAS: 1310-73-2)	PEL	1 mg/m <sup>3</sup>		irritating to mucous membranes (eyes, respiratory system) and skin
	NPK-P	2 mg/m <sup>3</sup>		
sodium azide (CAS: 26628-22-8)	PEL	0,1 mg/m <sup>3</sup>	0,370	skin penetration is significantly involved during exposure, irritating to mucous membranes (eyes, respiratory system) and skin
	NPK-P	0,3 mg/m <sup>3</sup>	0,370	
methanol (CAS: 67-56-1)	PEL	250 mg/m <sup>3</sup>	0,751	skin penetration is significantly involved during exposure
	NPK-P	1000 mg/m <sup>3</sup>	0,751	

## European Union

## Commission Directive 2000/39/EC

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

## European Union

## Commission Directive 2006/15/EC

Substance name (component)	Type	Value	Note
methanol (CAS: 67-56-1)	OEL 8 hours	260 mg/m <sup>3</sup>	Skin
	OEL 8 hours	200 ppm	

## Biological limit values

## Czech Republic

## Decree No. 107/2017 Coll.

Name	Parameter	Value	Tested material	Time of sampling
methanol (CAS: 67-56-1)	methanol	15 mg/l	Urine	End of shift
		0,47 mmol/l		

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**8.2. Exposure controls**

Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

**Eye/face protection**

It is not needed.

**Skin protection**

When handling in long-term or repeatedly, use protective gloves.

**Respiratory protection**

It is not needed.

**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	dark yellow
Odour	without fragrance
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available
Flammability	data not available
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	8-9 (undiluted at 20 °C)
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.

**10.5. Incompatible materials**

Unknown.

**10.6. Hazardous decomposition products**

Not developed under normal uses. Dangerous outcomes such as carbon monoxide and carbon dioxide are formed at high temperature and in fire.

**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.

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**Acute toxicity**

Based on available data the classification criteria are not met.  
ethanol

Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD <sub>50</sub>	10470 mg/kg		Rat		
Dermal	LD <sub>50</sub>	15800 mg/kg		Rat		
Inhalation	LC <sub>50</sub>	30000 mg/m <sup>3</sup>		Rat		

methanol

Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD <sub>50</sub>	5628 mg/kg		Rat (Rattus norvegicus)		
Dermal	LD <sub>50</sub>	15800 mg/kg		Rabbit		

sodium azide

Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD <sub>50</sub>	27 mg/kg bw				
Inhalation	LC <sub>50</sub>	54 mg/m <sup>3</sup>	4 hours	Rat		

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Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	42600 mg/kg				Calculation of value
Dermal	ATE	646700 mg/kg				Calculation of value
Inhalation (vapor)	ATE	6467 mg/l				Calculation of value

**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**

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.

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

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**Acute toxicity**

Data not available.  
ethanol

Parameter	Value	Exposure time	Species	Environment
LC <sub>50</sub>	11200 mg/l	96 hours	Fish	Fresh water
EC <sub>50</sub> /LC <sub>50</sub>	5012 mg/l		Invertebrates	Fresh water
EC <sub>50</sub> /LC <sub>50</sub>	857 mg/l		Invertebrates	Salt water
EC <sub>50</sub> /LC <sub>50</sub>	275 mg/l		Algae	Fresh water
EC <sub>50</sub> /LC <sub>50</sub>	1970 mg/l		Algae	Salt water
EC <sub>50</sub> /LC <sub>50</sub>	4432 mg/l		Higher plants	Fresh water
LC <sub>50</sub>	633 mg/kg of dry substance of soil		Higher plants	
EC <sub>50</sub> /LC <sub>50</sub>	5800 mg/l		Aquatic microorganisms	

methanol

Parameter	Value	Exposure time	Species	Environment
LC <sub>50</sub>	15400 mg/kg	96 hours	Fish (Lepomis macrochirus)	
EC <sub>50</sub>	>10000 mg/l	48 hours	Daphnia (Daphnia magna)	
IC <sub>50</sub>	22000 mg/l	48 hours	Algae (Scenedesmus capricornutum)	

sodium azide

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

**Chronic toxicity**

ethanol

Parameter	Value	Exposure time	Species	Environment
NOEC	9.6 mg/l		Invertebrates	Fresh water
NOEC	79 mg/l		Invertebrates	Salt water
NOEC	115 mg/l		Algae	Fresh water
NOEC	1580 mg/l		Algae (Selenastrum capricornutum)	Salt water
NOEC	280 mg/l		Higher plants	Salt water

**12.2. Persistence and degradability**

Data not available.

**12.3. Bioaccumulative potential**

Not available.

**12.4. Mobility in soil**

Not available.

**12.5. Results of PBT and vPvB assessment**

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**

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.

**12.7. Other adverse effects**

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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. Proceed in accordance with valid regulations on waste disposal. 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

## 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).

## Restrictions pursuant to Annex XVII of Regulation (EC) No. 1907/2006 (REACH), as amended

methanol

Restriction	Conditions of restriction
69	Shall not be placed on the market to the general public after 9 May 2019 in windscreen washing or defrosting fluids, in a concentration equal to or greater than 0,6 % by weight.

## 15.2. Chemical safety assessment

not available

## SECTION 16: Other information



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**A list of standard risk phrases used in the safety data sheet**

H225	Highly flammable liquid and vapour.
H300	Fatal if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H370	Causes damage to organs.
H371	May cause damage to organs.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H301+H311+H331	Toxic if swallowed, in contact with skin or if inhaled.

**A list of additional standard phrases used in the safety data sheet**

EUH032	Contact with acids liberates very toxic gas.
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**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**

ADR	European agreement concerning the international carriage of dangerous goods by road
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
EC <sub>50</sub>	Concentration of a substance when it is affected 50% of the population
EINECS	European Inventory of Existing Commercial Chemical Substances
EmS	Emergency plan
EU	European Union
EuPCS	European Product Categorisation System
IATA	International Air Transport Association
IBC	International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
IC <sub>50</sub>	Concentration causing 50% blockade
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 <sub>50</sub>	Lethal concentration of a substance in which it can be expected death of 50% of the population
LD <sub>50</sub>	Lethal dose of a substance in which it can be expected death of 50% of the population
log K <sub>ow</sub>	Octanol-water partition coefficient
NOEC	No observed effect concentration
NPK	Maximum admissible concentration
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic
PEL	Permissible Exposure Limit
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Agreement on the transport of dangerous goods by rail
UN	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

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VOC	Volatile organic compounds
vPvB	Very Persistent and very Bioaccumulative
Acute Tox.	Acute toxicity
Aquatic Acute	Hazardous to the aquatic environment
Aquatic Chronic	Hazardous to the aquatic environment (chronic)
Flam. Liq.	Flammable liquid
Skin Corr.	Skin corrosion
STOT SE	Specific target organ toxicity - single exposure

**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**

For in vitro diagnostic use only.

**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 4.0 replaces the SDS version from 20 May 2021. Changes were made in sections 2, 13, 15 and 16.

**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.