

## URINORM N

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**

Substance / mixture	URINORM N
Number	mixture
UFI	REG00053
Other mixture names	FXKT-1J5U-JE79-371U
	URINORM

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

Urinorm N is a part of URINORM Control Urines, a liquid synthetic material with concentration within the normal ranges. 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
VAT Reg No	CZ26918846
Phone	+420 517 077 111
E-mail	msds@erba.com
Web address	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 classified as dangerous.

Skin Sens. 1A, H317

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

**Most serious adverse effects on human health and the environment**

May cause an allergic skin reaction.

**2.2. Label elements****Hazard pictogram****Signal word**

Warning

## URINORM N

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

**Hazardous substances**

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one

**Hazard statements**

H317 May cause an allergic skin reaction.

**Precautionary statements**

P280 Wear protective gloves/protective clothing/eye protection.  
 P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.  
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

**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.

**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: 613-167-00-5 CAS: 55965-84-9	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one	<0,0025	Acute Tox. 3, H301 Acute Tox. 2, H310+H330 Skin Corr. 1C, H314 Skin Sens. 1A, H317 Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100) EUH071 Specific concentration limit: Eye Irrit. 2, H319: $0.06\% \leq C < 0.6\%$ Skin Sens. 1A, H317: $C \geq 0.0015\%$ Skin Irrit. 2, H315: $0.06\% \leq C < 0.6\%$ Skin Corr. 1C, H314: $C \geq 0.6\%$ Eye Dam. 1, H318: $C \geq 0.6\%$	1

**Notes**

- 1 Note B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid ... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

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.

## URINORM N

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

**If on skin**

Remove contaminated clothes. Wash the affected area with plenty of water, lukewarm if possible. Soap, soap solution or shampoo should be used if there is no skin injury. Provide medical treatment if skin irritation persists.

**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. Rinsing should continue at least for 10 minutes.

**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**

May cause an allergic skin reaction. Irritant effects, sensitization.

**If in eyes**

Not expected.

**If swallowed**

Irritation, nausea.

**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 according to the location of the fire.

**Unsuitable extinguishing media**

Not defined.

**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.

**5.3. Advice for firefighters**

Use a self-contained breathing apparatus and full-body protective clothing. Do not allow run-off of contaminated fire extinguishing material to enter drains or surface and ground water.

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

Use personal protective equipment for work. 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**

Spilled product should be covered with suitable (non-flammable) absorbing material (sand, diatomaceous earth, earth and other suitable absorption materials); to be contained in well closed containers and removed as per the Section 13. In the event of leakage of the substantial amount of the product, inform fire brigade and other competent bodies. After removal of the product, wash the contaminated site with plenty of water. Do not use solvents.

**6.4. Reference to other sections**

See the Section 7, 8 and 13.

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

Prevent contact with skin and eyes. 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.

## URINORM N

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

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****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**

Hand protection: Protective gloves resistant to the product. Contaminated skin should be washed thoroughly.

**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	light 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	5-6,5 (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.

## URINORM N

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

**10.4. Conditions to avoid**

The product is stable and no degradation occurs under normal use. Avoid exposure to heat and solar radiation.

**10.5. Incompatible materials**

Heavy metals, strong oxidizing agents and strong acids.

**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.

**Acute toxicity**

Based on available data the classification criteria are not met.

URINORM N

Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	4082000 mg/kg				Calculation of value
Dermal	ATE	2041000 mg/kg				Calculation of value
Inhalation (vapor)	ATE	20410 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**

May cause an allergic skin reaction.

**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****Acute toxicity**

Data not available.

**12.2. Persistence and degradability**

Data not available.

**12.3. Bioaccumulative potential**

Not available.

**12.4. Mobility in soil**

Not available.

## URINORM N

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

**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**

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.

**Waste type code**

16 05 06 laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals \*

**Packaging waste type code**

15 01 10 packaging containing residues of or contaminated by hazardous substances \*

(\*) - Hazardous waste according to Directive 2008/98/EC on hazardous waste

**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

## URINORM N

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

**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).

**15.2. Chemical safety assessment**

not available

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

H301	Toxic if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
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.
H310+H330	Fatal in contact with skin or if inhaled.

**Guidelines for safe handling used in the safety data sheet**

P280	Wear protective gloves/protective clothing/eye protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.

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

EUH071	Corrosive to the respiratory tract.
--------	-------------------------------------

**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
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
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

## URINORM N

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

IUPAC	International Union of Pure and Applied Chemistry
log K <sub>ow</sub>	Octanol-water partition coefficient
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
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)
Eye Dam.	Serious eye damage
Skin Corr.	Skin corrosion
Skin Sens.	Skin sensitization

**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.