

## zone BILI

Creation date 15th February 2023  
Revision date Version 1.0

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

- 1.1. Product identifier** zone BILI  
Substance / mixture mixture
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**  
**Mixture's intended use**  
Diagnostic strips are intended for semi-quantitative analysis of urine. The BILI zone is used to determine bilirubin in the urine. Diagnostic strips are intended for in vitro diagnostic use by an authorized and professionally trained person.  
**Main intended use**  
PC-MED-OTH Other medical devices  
**Secondary uses**  
PC-TEC-19 Reagents and laboratory chemicals  
**Mixture uses advised against**  
The product should not be used in ways other than those referred in Section 1.
- 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

**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**  
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.

**SECTION 3: Composition/information on ingredients**

- 3.2. Mixtures**  
**Chemical characterization**  
A solid mixture of substances on a carrier. Mixture of substances 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: 37267-86-0	Metaphosphoric acid	0,3	Skin Corr. 1C, H314	
CAS: 5949-29-1 EC: 201-069-1	Citric acid monohydrate	<0,2	Eye Irrit. 2, H319	1

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Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
CAS: 151-21-3 EC: 205-788-1	Sodium dodecyl sulphate	0,004	Flam. Sol. 2, H228 Acute Tox. 4, H302+H332 Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Chronic 3, H412 Specific concentration limit: Eye Irrit. 2, H319: 10 % ≤ C < 20 % Eye Dam. 1, H318: C ≥ 20 %	
CAS: 387-41-7 EC: 206-858-4	2,6-dichlorobenzenediazonium tetrafluoroborate	0,003	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335	

**Notes**

1 A substance for which exposure limits are set.

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**

Unlikely.

**If on skin**

Normal washing of the skin is considered sufficient; If nevertheless symptoms do occur, contact a physician.

**If in eyes**

If used correctly according to the instructions, eye contact is unlikely.

**If swallowed**

Unlikely. If swallowed rinse mouth with plenty of water provided person is conscious. Call a doctor if you feel unwell.

**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**

Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.

**Unsuitable extinguishing media**

No unsuitable extinguishing media are known.

**5.2. Special hazards arising from the substance or mixture**

Fires in the immediate vicinity may cause the development of dangerous vapours.

**5.3. Advice for firefighters**

Use breathing apparatus. Wear protective clothing. The mixture is not flammable. The safety measure should be adapted to the flammable substances in the surroundings.

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

Observe the principles of work safety in chemical laboratories. Follow the instructions in Sections 7 and 8. Do not eat, drink or smoke.

**6.2. Environmental precautions**

Due to amount of chemical substances in a mixture, an impact on the environment is not expected.

**6.3. Methods and material for containment and cleaning up**

Store contaminated material in containers for hazardous waste collection.

**6.4. Reference to other sections**

See the Section 7, 8 and 13.

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

Observe the normal operating procedures for handling chemical substances and mixtures. Observe the principles of safety work in chemical laboratories. Do not eat, drink and smoke in work areas. Wash hands after use. Preventive skin protection (barrier creams/ointments) is recommended. Remove contaminated clothing and protective equipment before entering eating areas.

**7.2. Conditions for safe storage, including any incompatibilities**

Diagnostic strips must be stored in well-closed original packaging in a dry and dark place at (+2 to +30) °C. The strips must be protected from the effect of air humidity, direct sunlight, elevated temperature and chemical vapors in the laboratory. If these storage conditions are observed, the diagnostic strips can be used until the time indicated on the package.

Storage class

13 - Other non-combustible solids

Storage temperature

min 2 °C, max 30 °C

**The specific requirements or rules relating to the substance/mixture**

This product is for in vitro diagnostic use only and should be used by trained personnel.

**7.3. Specific end use(s)**

For professional use only.

**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 41/2020 Coll.**

Substance name (component)	Type	Value
Citric acid monohydrate (CAS: 5949-29-1)	PELc	4,0 mg/m <sup>3</sup>

**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**

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

solid

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Colour	mixture containing generic product identifier 'colorant'
Odour	odourless without fragrance
Melting point/freezing point	not applicable
Boiling point or initial boiling point and boiling range	not applicable
Flammability	The product is non-flammable.
Lower and upper explosion limit	data not available
Flash point	not applicable
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**

Under normal conditions of use and storage the mixture is stable. When used in the standard way, there is not any dangerous reaction with other substances.

**10.2. Chemical stability**

Sensitivity to light. Hygroscopic. The product is stable until the expiration date shown on the box and on the labels when stored in accordance with section 7.2a.

**10.3. Possibility of hazardous reactions**

Unknown.

**10.4. Conditions to avoid**

The strips must be protected from the effect of air humidity, direct sunlight, elevated temperature and chemical vapors in the laboratory.

**10.5. Incompatible materials**

Protect against strong acids, bases and oxidizing agents.

**10.6. Hazardous decomposition products**

Fires in the immediate vicinity may cause the development of dangerous vapours.

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

Inhalation of solvent vapors above values exceeding exposure limits for working environment may result in acute inhalation poisoning, depending on the level of concentration and exposure time. No toxicological data is available for the mixture.

**Acute toxicity**

Based on available data the classification criteria are not met.

**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.

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**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**

The mixture is not classified as toxic to environment.

**12.2. Persistence and degradability**

No data 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**

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.

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**Waste type code**

- 18 01 03\* wastes whose collection and disposal is subject to special requirements in order to prevent infection
- 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

**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 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.

**15.2. Chemical safety assessment**

not available

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

- H228 Flammable solid.
- H314 Causes severe skin burns and eye damage.
- H315 Causes skin irritation.
- H318 Causes serious eye damage.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H412 Harmful to aquatic life with long lasting effects.
- H302+H332 Harmful if swallowed or if inhaled.

**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

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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
IUPAC	International Union of Pure and Applied Chemistry
log Kow	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 Chronic	Hazardous to the aquatic environment (chronic)
Eye Dam.	Serious eye damage
Flam. Sol.	Flammable solid
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**

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.

**More information**

Classification procedure - calculation method.

**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.