

## zone LEUKO

|               |                    |         |     |
|---------------|--------------------|---------|-----|
| Creation date | 16th February 2023 |         |     |
| Revision date | 11th February 2025 | Version | 3.0 |

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

|                     |            |
|---------------------|------------|
| zone LEUKO          |            |
| Substance / mixture | mixture    |
| Number              | zóna Leuko |

**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 LEUKO zone is used in clinical biochemistry for the semi-quantitative determination of leukocytes in 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**

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 not classified as dangerous according to Regulation (EC) No 1272/2008.

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

Under normal conditions of use, the mixture does not cause adverse effects to humans and to the environment.

**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. Dust may form explosive mixture with air.

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

A solid mixture of substances on a carrier.

**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: 005-007-00-2<br>CAS: 10043-35-3<br>EC: 233-139-2 | boric acid     | <0.3                | Repr. 1B, H360FD   | 1, 2, 3 |

**Notes**

- Note 11: The classification of mixtures as reproductive toxicant is necessary if the sum of the concentrations of individual boron compounds that are classified as reproductive toxicant in the mixture as placed on the market is  $\geq 0,3$  %.*
- Substance of very high concern - SVHC.*
- 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**

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.

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**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.

**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.

**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

Colour mixture containing generic product identifier "colorant"

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|  |                               |
|--|-------------------------------|
| 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**

none

**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**

No known hazardous reactions.

**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, oxidizing agents and heavy metals.

**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**

No toxicological data is available for the mixture.

**Acute toxicity**

Based on available data the classification criteria are not met.

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|------------------------|-----------|-------------|---------------|---------|-----|----------------------|
| Route of exposure      | Parameter | Value       | Exposure time | Species | Sex | Value determination  |
| Inhalation (dust/mist) | ATE       | 147059 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.

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**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**

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**

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.

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**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**

- 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 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).

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

boric acid

| Restriction | Conditions of restriction  |
|-------------|--|
| 30          | <p>1. Shall not be placed on the market, or used,</p> <ul style="list-style-type: none"> <li>— as substances,</li> <li>— as constituents of other substances, or,</li> <li>— in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than: <ul style="list-style-type: none"> <li>— either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,</li> <li>— the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008.</li> </ul> </li> </ul> <p>Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows:</p> <p>“Restricted to professional users”.</p> <p>2. By way of derogation, paragraph 1 shall not apply to:</p> <ul style="list-style-type: none"> <li>(a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC;</li> <li>(b) cosmetic products as defined by Directive 76/768/EEC;</li> <li>(c) the following fuels and oil products: <ul style="list-style-type: none"> <li>— motor fuels which are covered by Directive 98/70/EC,</li> <li>— mineral oil products intended for use as fuel in mobile or fixed combustion plants,</li> <li>— fuels sold in closed systems (e.g. liquid gas bottles);</li> </ul> </li> <li>(d) artists' paints covered by Regulation (EC) No 1272/2008;</li> <li>(e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date.</li> <li>(f) devices covered by Regulation (EU) 2017/745.</li> </ul> |

**15.2. Chemical safety assessment**

not available

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

H360FD May damage fertility. May damage the unborn child.

**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  |

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|         |   |
|---------|---|
| 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  |
| PMT     | Persistent, mobile and toxic  |
| ppm     | Parts per million   |
| REACH   | Registration, Evaluation, Authorisation and Restriction of Chemicals                              |
| Repr.   | Reproductive toxicity   |
| 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  |
| 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 Thursday, 30 May 2024. Changes were made in sections 2, 11, 12, 13 and 16.

**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.