

ELite HEM Calibrator

| | | | |
|---------------|------------------|---------|-----|
| Creation date | 21st August 2020 | Version | 2.0 |
| Revision date | 07th June 2024 | | |

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

| | |
|---------------------|------------------------------|
| Substance / mixture | ELite HEM Calibrator mixture |
| Number | HEM00012 |
| Other mixture names | ELITE HEM CALIBRATOR 3ML |

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

ELite HEM Calibrator is designed for use in the calibration of hematology analyzers. Please refer to the assay table for specific instrument models.

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.

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 |
|---|---------------------|---------------------|---|------|
| Index: 019-002-00-8 CAS: 1310-58-3 EC: 215-181-3 | potassium hydroxide | <0,1 | Acute Tox. 4, H302 Skin Corr. 1A, H314 Specific concentration limit: Skin Irrit. 2, H315: 0.5 % ≤ C < 2 % Skin Corr. 1A, H314: C ≥ 5 % Skin Corr. 1B, H314: 2 % ≤ C < 5 % Eye Irrit. 2, H319: 0.5 % ≤ C < 2 % | 1 |
| Index: 011-004-00-7 CAS: 26628-22-8 EC: 247-852-1 | sodium azide | <0,01 | Acute Tox. 2, H300 Acute Tox. 1, H310 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 | 1 |
| Index: 613-140-00-8 CAS: 66-81-9 EC: 200-636-0 | cycloheximide (ISO) | <0,01 | Acute Tox. 2, H300 Muta. 2, H341 Repr. 1B (***) , H360D Aquatic Chronic 2, H411 | 2 |

Notes

*** reproductive toxicity: supplementary letters specify whether fetal harm (d) or fertility harm (f) may occur

1 A substance for which exposure limits are set.

2 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. Wash skin with water thoroughly or use a shower. In case of skin irritation or allergic reactions see a physician.

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.

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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. The mixture is not flammable.

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. Observe the principles of work safety in chemical laboratories.

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**

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.

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)

Intended 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 330/2023 Coll.**

| Substance name (component) | Type | Value | Note |
|--------------------------------------|-------|-----------------------|--|
| potassium hydroxide (CAS: 1310-58-3) | PEL | 1 mg/m ³ | irritating to mucous membranes (eyes, respiratory system) and skin |
| | NPK-P | 2 mg/m ³ | |
| sodium azide (CAS: 26628-22-8) | PEL | 0,1 mg/m ³ | skin penetration is significantly involved during exposure, irritating to mucous membranes (eyes, respiratory system) and skin |

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Czech Republic

Government Regulation 330/2023 Coll.

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

United Kingdom

EH40/2005 Workplace exposure limits (Fourth Edition 2020)

| Substance name (component) | Type | Value | Note |
|---|-----------|-----------------------|---|
| potassium hydroxide (CAS: 1310-58-3) | WEL 15min | 2 mg/m ³ | |
| sodium azide (as NaN ₃) (CAS: 26628-22-8) | WEL 8h | 0,1 mg/m ³ | Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity. |
| | WEL 15min | 0,3 mg/m ³ | |

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

Halfmask with a filter against organic vapours or a self-contained breathing apparatus as appropriate if exposure limit values of substances are exceeded or in a poorly ventilated environment.

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 | data not available |
| Odour | data not available |
| 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. |

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| | |
|---|--------------------|
| 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

| | |
|----------------------|---|
| Oxidising properties | The product has no oxidizing properties. |
| Explosive properties | The product does not have explosive properties. |

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

Not known. 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.

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

Data for the mixture are not available. Based on the available data, the criteria for classification of the mixture are not met.

| potassium hydroxide | | | | | |
|---------------------|------------------|---------------|---------------|---------|-----|
| Route of exposure | Parameter | Value | Exposure time | Species | Sex |
| Oral | LD ₅₀ | 333-388 mg/kg | | Rat | |

Skin corrosion/irritation

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Serious eye damage/irritation

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

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Respiratory or skin sensitisation

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Germ cell mutagenicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Carcinogenicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Reproductive toxicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Toxicity for specific target organ - single exposure

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Toxicity for specific target organ - repeated exposure

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Aspiration hazard

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture 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**

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

12.2. Persistence and degradability

No data are available for either the mixture or the components.

12.3. Bioaccumulative potential

No data are available for either the mixture or the components.

12.4. Mobility in soil

No data are available for either the mixture or the components.

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

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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).

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

cycloheximide (ISO)

| Restriction | Conditions of restriction |
|-------------|---|
| 30 | <p>Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30:</p> <p>1. Shall not be placed on the market, or used,</p> <ul style="list-style-type: none"> – as substances, – as constituents of other substances, or, – 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"> – either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, – the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008. <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"> (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC; (c) the following fuels and oil products: <ul style="list-style-type: none"> – motor fuels which are covered by Directive 98/70/EC, – mineral oil products intended for use as fuel in mobile or fixed combustion plants, – fuels sold in closed systems (e.g. liquid gas bottles); (d) artists’ paints covered by Regulation (EC) No 1272/2008; (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. (f) devices covered by Regulation (EU) 2017/745. |

15.2. Chemical safety assessment

not available

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

| | |
|-------|--|
| H300 | Fatal if swallowed. |
| H302 | Harmful if swallowed. |
| H310 | Fatal in contact with skin. |
| H314 | Causes severe skin burns and eye damage. |
| H315 | Causes skin irritation. |
| H319 | Causes serious eye irritation. |
| H341 | Suspected of causing genetic defects. |
| H360D | May damage the unborn child. |
| H373 | May cause damage to organs through prolonged or repeated exposure. |
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |
| H411 | 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

| | |
|-----|---|
| ADR | European agreement concerning the international carriage of dangerous goods by road |
| BCF | Bioconcentration Factor |
| CAS | Chemical Abstracts Service |

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|------------------|---|
| 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 |
| 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 |
| 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) |
| Muta. | Germ cell mutagenicity |
| Repr. | Reproductive toxicity |
| Skin Corr. | Skin corrosion |
| STOT RE | Specific target organ toxicity - repeated 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.

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

The version 2.0 replaces the SDS version from 21 August 2020. Changes were made in sections 1, 2, 11, 12, 15 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.