

EC cartridge VET_R1

| | | | |
|---------------|-----------------|---------|-----|
| Creation date | 31st May 2024 | Version | 1.1 |
| Revision date | 23rd April 2025 | | |

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

| | |
|---|---------------------|
| Substance / mixture | EC cartridge VET_R1 |
| Number | mixture |
| Other mixture names | VET00002 |
| EC cartridge VET XS plus iCa, reagent 1 | |

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

EC cartridge is an IVD kit intended for calibration and quantification of sodium (Na+), potassium (K+), ionized calcium (iCa2+) and chloride (Cl-) on the EC 90 analyzer series. Intended only for IVD use by a 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 |

Email address for a 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**Signal word**

none

Supplemental information

EUH208 Contains reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one. May produce an allergic reaction.

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.

EC cartridge VET_R1

| | | | |
|---------------|-----------------|---------|-----|
| Creation date | 31st May 2024 | Version | 1.1 |
| Revision date | 23rd April 2025 | | |

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: 011-002-00-6 CAS: 1310-73-2 EC: 215-185-5 Registration number: 01-2119457892-27-0000 | sodium hydroxide | 0.2 | Met. Corr. 1, H290 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 % | 2 |
| Index: 017-013-00-2 CAS: 10043-52-4 EC: 233-140-8 | calcium chloride | <0.02 | Eye Irrit. 2, H319 | 2 |
| 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 | 0.00015 | 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 % ≤ C < 0.6 % Skin Sens. 1A, H317: C ≥ 0.0015 % Skin Irrit. 2, H315: 0.06 % ≤ C < 0.6 % Skin Corr. 1C, H314: C ≥ 0.6 % Eye Dam. 1, H318: C ≥ 0.6 % | 1 |

Notes

- 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.
- 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

Terminate the exposure immediately; move the affected person to fresh air.

If on skin

Remove contaminated clothes. Wash with plenty of soap and water.

EC cartridge VET_R1

| | | | |
|---------------|-----------------|---------|-----|
| Creation date | 31st May 2024 | | |
| Revision date | 23rd April 2025 | Version | 1.1 |

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.

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.

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. Protect against frost.

Storage temperature

min 2 °C, max 30 °C

7.3. Specific end use(s)

The kit is designed 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.

EC cartridge VET_R1

| | | | |
|---------------|-----------------|---------|-----|
| Creation date | 31st May 2024 | Version | 1.1 |
| Revision date | 23rd April 2025 | | |

Czech Republic

Government Regulation 20/2025 Coll.

| Substance name (component) | Type | Value |
|------------------------------------|-------|---------------------|
| sodium hydroxide (CAS: 1310-73-2) | PEL | 1 mg/m ³ |
| | NPK-P | 2 mg/m ³ |
| calcium chloride (CAS: 10043-52-4) | PEL | 2 mg/m ³ |
| | NPK-P | 4 mg/m ³ |

Notes

Irritating to mucous membranes (eyes, respiratory system) and skin.

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

Wear safety goggles.

Skin protection

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

Respiratory protection

Not required with adequate ventilation.

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 | clear |
| 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. |
| 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 | 7.5 (undiluted at 20 °C) |
| Kinematic viscosity | data not available |
| Solubility in water | data not available |
| Solubility in fats | 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 |
| Form | Clear colourless liquid |

9.2. Other information

| | |
|----------------------|---|
| Evaporation rate | data not available |
| 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

EC cartridge VET_R1

| | | | |
|---------------|-----------------|---------|-----|
| Creation date | 31st May 2024 | | |
| Revision date | 23rd April 2025 | Version | 1.1 |

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. 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**

No toxicological data is available for the mixture.

Acute toxicity

Based on available data the classification criteria are not met.

| EC cartridge VET_R1 | | | | | | |
|---------------------|-----------|----------------|---------------|---------|-----|----------------------|
| Route of exposure | Parameter | Value | Exposure time | Species | Sex | Value determination |
| Oral | ATE | 16993464 mg/kg | | | | Calculation of value |
| Dermal | ATE | 33333333 mg/kg | | | | Calculation of value |
| Inhalation (gases) | ATE | 66666667 ppm | | | | Calculation of value |

| calcium chloride | | | | | | |
|-------------------|------------------|------------|---------------|---------|-----|---------------------|
| Route of exposure | Parameter | Value | Exposure time | Species | Sex | Value determination |
| Dermal | LD ₅₀ | 2630 mg/kg | | Rat | | |

| sodium hydroxide | | | | | | |
|-------------------|------------------|------------|---------------|---------|-----|---------------------|
| Route of exposure | Parameter | Value | Exposure time | Species | Sex | Value determination |
| Oral | LD ₅₀ | 325 mg/kg | | Rat | | |
| Dermal | LD ₅₀ | 1350 mg/kg | | Rabbit | | |
| Oral | LD ₅₀ | 500 mg/kg | | Rabbit | | |
| Dermal | LD ₅₀ | 40 mg/kg | | Mouse | | |

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.

EC cartridge VET_R1

| | | | |
|---------------|-----------------|---------|-----|
| Creation date | 31st May 2024 | Version | 1.1 |
| Revision date | 23rd April 2025 | | |

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

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

11.2. Information on other hazards**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.

Other information

not available

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.

Acute toxicity

| calcium chloride | | | | |
|------------------|------------|---------------|----------------------------|-------------|
| Parameter | Value | Exposure time | Species | Environment |
| LC ₅₀ | 10650 mg/l | 96 hours | Fish (Lepomis macrochirus) | |
| EC ₅₀ | 144 mg/l | 48 hours | Daphnia (Daphnia magna) | |
| IC ₅₀ | 3130 mg/l | 120 hours | Algae | |

| sodium hydroxide | | | | |
|------------------|-----------|---------------|----------------------------|-------------|
| Parameter | Value | Exposure time | Species | Environment |
| EC ₅₀ | 76 mg/l | 24 hours | Daphnia (Daphnia magna) | |
| EC ₅₀ | 145 mg/l | 24 hours | Fish (Poecilia reticulata) | |
| EC ₅₀ | 40.4 mg/l | 48 hours | Daphnia (Daphnia magna) | |
| LC ₅₀ | 160 mg/l | 24 hours | Fish (Carassius auratus) | |

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.

EC cartridge VET_R1

| | | | |
|---------------|-----------------|---------|-----|
| Creation date | 31st May 2024 | | |
| Revision date | 23rd April 2025 | Version | 1.1 |

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

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).

EC cartridge VET_R1

| | | | |
|---------------|-----------------|---------|-----|
| Creation date | 31st May 2024 | | |
| Revision date | 23rd April 2025 | Version | 1.1 |

15.2. Chemical safety assessment

not available

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

| | |
|-----------|---|
| EUH071 | Corrosive to the respiratory tract. |
| EUH208 | Contains reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one. May produce an allergic reaction. |
| H290 | May be corrosive to metals. |
| H301 | Toxic if swallowed. |
| H310+H330 | Fatal in contact with skin or if inhaled. |
| 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. |

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

| | |
|---------------------|---|
| Acute Tox. | Acute toxicity |
| ADR | Agreement concerning the international carriage of dangerous goods by road |
| Aquatic Acute | Hazardous to the aquatic environment |
| Aquatic Chronic | Hazardous to the aquatic environment (chronic) |
| 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 ₅₀ | 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 |
| Eye Dam. | Serious eye damage |
| Eye Irrit. | Eye irritation |
| IATA | International Air Transport Association |
| IBC | International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals |
| IC ₅₀ | 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 ₅₀ | Lethal concentration of a substance in which it can be expected death of 50% of the population |
| LD ₅₀ | Lethal dose of a substance in which it can be expected death of 50% of the population |
| log K _{ow} | Octanol-water partition coefficient |
| Met. Corr. | Corrosive to metals |
| NPK | Maximum admissible concentration |

EC cartridge VET_R1

| | | | |
|---------------|-----------------|---------|-----|
| Creation date | 31st May 2024 | | |
| Revision date | 23rd April 2025 | Version | 1.1 |

| | |
|-------------|---|
| 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 |
| RID | Agreement on the transport of dangerous goods by rail |
| Skin Corr. | Skin corrosion |
| Skin Irrit. | Skin irritation |
| Skin Sens. | Skin sensitization |
| UN number | 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 2.0 replaces the SDS version from 21 June 2022. Changes were made in sections 2, 11, 15 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.