

## EC cartridge plus iCa\_R1

Creation date	12th March 2021	Version	2.0
Revision date	31st May 2024		

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

- 1.1. Product identifier**  
Substance / mixture EC cartridge plus iCa\_R1 mixture  
Number REG00066; REG00061; REG00062; REG00063  
Other mixture names  
EC cartridge XS plus iCa; EC cartridge S plus iCa; EC cartridge M plus iCa; EC cartridge L plus iCa, calibration solution 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<sup>+</sup>), potassium (K<sup>+</sup>), ionized calcium (iCa<sup>2+</sup>) and chloride (Cl<sup>-</sup>) 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  
**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  
**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.

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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: 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 Eye Dam. 1, H318 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.

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**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.

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## Czech Republic

## Government Regulation 330/2023 Coll.

Substance name (component)	Type	Value	Note
sodium hydroxide (CAS: 1310-73-2)	PEL	1 mg/m <sup>3</sup>	irritating to mucous membranes (eyes, respiratory system) and skin
	NPK-P	2 mg/m <sup>3</sup>	
calcium chloride (CAS: 10043-52-4)	PEL	2 mg/m <sup>3</sup>	irritating to mucous membranes (eyes, respiratory system) and skin
	NPK-P	4 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**

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.

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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**

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.

calcium chloride					
Route of exposure	Parameter	Value	Exposure time	Species	Sex
Dermal	LD <sub>50</sub>	2630 mg/kg		Rat	

sodium hydroxide					
Route of exposure	Parameter	Value	Exposure time	Species	Sex
Oral	LD <sub>50</sub>	325 mg/kg		Rat	
Dermal	LD <sub>50</sub>	1350 mg/kg		Rabbit	
Oral	LD <sub>50</sub>	500 mg/kg		Rabbit	
Dermal	LD <sub>50</sub>	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.

**Reproductive toxicity**

Based on available data the classification criteria are not met.

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**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**

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.

**Acute toxicity**

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

sodium hydroxide				
Parameter	Value	Exposure time	Species	Environment
EC <sub>50</sub>	76 mg/l	24 hours	Daphnia (Daphnia magna)	
EC <sub>50</sub>	145 mg/l	24 hours	Fish (Poecilia reticulata)	
EC <sub>50</sub>	40.4 mg/l	48 hours	Daphnia (Daphnia magna)	
LC <sub>50</sub>	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.

**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.

**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).

**15.2. Chemical safety assessment**

not available

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

H290	May be corrosive to metals.
H301	Toxic if swallowed.
H314	Causes severe skin burns and eye damage.

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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.

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

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.

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
EC <sub>50</sub>	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
IATA	International Air Transport Association
IBC	International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
IC <sub>50</sub>	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 <sub>50</sub>	Lethal concentration of a substance in which it can be expected death of 50% of the population
LD <sub>50</sub>	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

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Acute Tox.	Acute toxicity
Aquatic Acute	Hazardous to the aquatic environment
Aquatic Chronic	Hazardous to the aquatic environment (chronic)
Eye Dam.	Serious eye damage
Met. Corr.	Corrosive to metals
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**

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.