

## CYSTATIN C Calibrator\_R1

Creation date	06th March 2019	Version	3.0
Revision date	23rd April 2024		

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

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Substance / mixture

mixture

Number

10010249

Other mixture names

CYS C CAL 1x2; ILT CYSTATIN C Calibrator

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

The kit is intended for immunoturbidimetric quantitative determination of Cystatin C in human serum.

**Main intended use**

PC-MED-OTH

Other medical devices

**Secondary uses**

PC-TEC-19

Reagents and laboratory chemicals

**The use descriptors**

PC 21

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

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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**

Aqueous solution of anorganic salts and organic components, mixture of the substances listed below with harmless products. Contains sodium azide (< 0.1 %) as preservative.

**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: 011-004-00-7 CAS: 26628-22-8 EC: 247-852-1	sodium azide	<0,1	Acute Tox. 2, H300 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1) EUH032	1

**Notes**

1 A substance for which exposure limits are set.

Full text of all classifications and hazard statements is given in the section 16.

**SECTION 4: First aid measures****4.1. Description of first aid measures**

Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet.

**If inhaled**

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

**If on skin**

After contact with skin, wash immediately with soap and plenty of water. Change contaminated clothing. In case of skin reactions, consult 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 mouth thoroughly with water. Induce vomiting. Have victim drink large quantities of water, with active charcoal if possible. Seek medical attention.

**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. Carbon dioxide (CO<sub>2</sub>), extinguishing powder or water spray/fog. Fight larger fires with water spray/fog or alcohol-resistant foam.

**Unsuitable extinguishing media**

not available

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

Nitrogen oxides (NO<sub>x</sub>), Oxides of phosphorus (P<sub>x</sub>O<sub>y</sub>), Carbon monoxide (CO) and Carbon dioxide (CO<sub>2</sub>).

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**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. Hazchem-Code: Collect contaminated firefighting water separately. Do not allow fire water to penetrate into surface or ground water.

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

Follow the instructions in the Sections 7 and 8. Avoid contact with the substance. Wear personal protection equipment. Do not breathe vapour/ aerosol. Provide adequate ventilation.

**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**

Soak up with absorbent, liquid-binding materials such as sand, siliceous earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance. Clean the contaminated area with.

**6.4. Reference to other sections**

See the Section 7, 8 and 13.

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

For use only by qualified technical staff. Provide adequate ventilation, and local exhaust as needed. Avoid contact with skin, eyes, and clothing. Do not inhale substance. After worktime and during work intervals the affected skin areas must be thoroughly cleaned. This product contains a substance with human origin. Even though tests on infectious diseases ended negative, this product should be handled as potentially infectious biomaterial. Refer additionally to chapter 11. Make sure that all applicable workplace limits are observed.

**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. Observe all local and national regulations for storage of water polluting products. Protect from heat and light. Keep away from food, drink and animal feeding stuffs.

Storage class

12 - Other non-combustible liquids

Storage temperature

min 2 °C, max 8 °C

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

Reagent for in-vitro diagnostics in human samples.

**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
sodium azide (CAS: 26628-22-8)	PEL	0,1 mg/m <sup>3</sup>	skin penetration is significantly involved during exposure, irritating to mucous membranes (eyes, respiratory system) and skin
	NPK-P	0,3 mg/m <sup>3</sup>	

**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 <sup>3</sup>	Skin

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## European Union

## Commission Directive 2000/39/EC

Substance name (component)	Type	Value	Note
sodium azide (CAS: 26628-22-8)	OEL 15 minutes	0,3 mg/m <sup>3</sup>	Skin

## United Kingdom

## EH40/2005 Workplace exposure limits (Fourth Edition 2020)

Substance name (component)	Type	Value	Note
sodium azide (as NaN <sub>3</sub> ) (CAS: 26628-22-8)	WEL 8h	0,1 mg/m <sup>3</sup>	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 <sup>3</sup>	

## 8.2. Exposure controls

Change contaminated clothing. When using do not eat, drink or smoke. Wash hands before breaks and after work. Have eye wash bottle or eye rinse ready at work place.

## Eye/face protection

Tightly sealed safety glasses according to EN 166.

## Skin protection

Lab coat. Protective gloves according to EN 374.

Glove material: Nitrile rubber-Breakthrough time: >480 min.

Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

## Respiratory protection

If all workplace limits are observed and good ventilation is ensured, no special precautions necessary.

## 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	colourless
Odour	odourless
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	data not available
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

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Density and/or relative density	data not available
Relative vapour density	data not available
Particle characteristics	data not available
Form	colourless liquid
<b>9.2. Other information</b>	
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

## 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. Protect against heat /sunlight.

## 10.5. Incompatible materials

Protect against strong acids, bases, oxidizing agents and heavy metals.

## 10.6. Hazardous decomposition products

Dangerous reactions may form very sensitive explosive metallic compounds. Nitrogen oxides (NO<sub>x</sub>), Oxides of phosphorus (P<sub>x</sub>O<sub>y</sub>), Carbon monoxide (CO) and Carbon dioxide (CO<sub>2</sub>).

## SECTION 11: Toxicological information

## 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

## Acute toxicity

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

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Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	27000 mg/kg				Calculation of value

sodium azide						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD <sub>50</sub>	27 mg/kg bw				
Inhalation	LC <sub>50</sub>	54 mg/m <sup>3</sup>	4 hours	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**

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

**Acute toxicity**

sodium azide				
Parameter	Value	Exposure time	Species	Environment
LC <sub>50</sub>	680 µg/l		Fish	Fresh water
EC <sub>50</sub> /LC <sub>50</sub>	400 µg/l		Invertebrates	Fresh water
EC <sub>50</sub> /LC <sub>50</sub>	150 µg/l		Invertebrates	Salt water
EC <sub>50</sub> /LC <sub>50</sub>	348 µg/l		Algae	Fresh water
EC <sub>50</sub> /LC <sub>50</sub>	5.6 mg/l		Microorganisms	
NOEC	30 µg/l		Microorganisms	

**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**

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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**

Slightly hazardous for water. Do not allow to enter into ground-water, surface water or drains.

**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.

**Packaging waste type code**

15 01 02 plastic packaging

**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

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## SECTION 16: Other information

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

H300	Fatal if swallowed.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

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

EUH032	Contact with acids liberates very toxic gas.
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**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
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 K <sub>ow</sub>	Octanol-water partition coefficient
NOEC	No observed effect concentration
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)

**Training guidelines**



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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 19 May 2022. Changes were made in sections 1, 2, 11, 15 and 16.

**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.