

CYSTATIN C_R2

| | | | |
|---------------|-----------------|---------|-----|
| Creation date | 06th March 2019 | Version | 3.0 |
| Revision date | 22nd April 2024 | | |

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

CYSTATIN C_R2

Substance / mixture

mixture

Number

10010248

Other mixture names

CYS C 1x5; ILT CYSTATIN C

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

The liquid reagents for immunoturbidimetric quantitative determination of Cystatin C in human serum and plasma.

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

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.

CYSTATIN C_R2

| | | | |
|---------------|-----------------|---------|-----|
| Creation date | 06th March 2019 | Version | 3.0 |
| Revision date | 22nd April 2024 | | |

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: 011-004-00-7 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 (CO₂), 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 mixtureNitrogen oxides (NO_x), Oxides of phosphorus (PxO_y), Carbon monoxide (CO) and Carbon dioxide (CO₂).

CYSTATIN C_R2

| | | | |
|---------------|-----------------|---------|-----|
| Creation date | 06th March 2019 | Version | 3.0 |
| Revision date | 22nd April 2024 | | |

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: bleaching agent 10%-solution.

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 ³ | skin penetration is significantly involved during exposure, irritating to mucous membranes (eyes, respiratory system) and skin |
| | NPK-P | 0,3 mg/m ³ | |

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 |

CYSTATIN C_R2

| | | | |
|---------------|-----------------|---------|-----|
| Creation date | 06th March 2019 | Version | 3.0 |
| Revision date | 22nd April 2024 | | |

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 ³ | Skin |

United Kingdom

EH40/2005 Workplace exposure limits (Fourth Edition 2020)

| Substance name (component) | Type | Value | Note |
|---|-----------|-----------------------|---|
| 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

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 |

CYSTATIN C_R2

| | | | |
|---------------|-----------------|---------|-----|
| Creation date | 06th March 2019 | Version | 3.0 |
| Revision date | 22nd April 2024 | | |

Density and/or relative density

data not available

Relative vapour density

data not available

Particle characteristics

data not available

Form

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

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 productsDangerous reactions may form very sensitive explosive metallic compounds. Nitrogen oxides (NO_x), Oxides of phosphorus (P_xO_y), Carbon monoxide (CO) and Carbon dioxide (CO₂).**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.

| CYSTATIN C_R2 | | | | | | |
|-------------------|-----------|-------------|---------------|---------|-----|----------------------|
| 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 ₅₀ | 27 mg/kg bw | | | | |
| Inhalation | LC ₅₀ | 54 mg/m ³ | 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.

CYSTATIN C_R2

| | | | |
|---------------|-----------------|---------|-----|
| Creation date | 06th March 2019 | Version | 3.0 |
| Revision date | 22nd April 2024 | | |

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 ₅₀ | 680 µg/l | | Fish | Fresh water |
| EC ₅₀ /LC ₅₀ | 400 µg/l | | Invertebrates | Fresh water |
| EC ₅₀ /LC ₅₀ | 150 µg/l | | Invertebrates | Salt water |
| EC ₅₀ /LC ₅₀ | 348 µg/l | | Algae | Fresh water |
| EC ₅₀ /LC ₅₀ | 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

CYSTATIN C_R2

| | | | |
|---------------|-----------------|---------|-----|
| Creation date | 06th March 2019 | | |
| Revision date | 22nd April 2024 | Version | 3.0 |

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

CYSTATIN C_R2

| | | | |
|---------------|-----------------|---------|-----|
| Creation date | 06th March 2019 | Version | 3.0 |
| Revision date | 22nd April 2024 | | |

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. |
|--------|--|

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 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 |
| 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

CYSTATIN C_R2

| | | | |
|---------------|-----------------|---------|-----|
| Creation date | 06th March 2019 | | |
| Revision date | 22nd April 2024 | Version | 3.0 |

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.

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.