

CRP-HS_R1

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|---------------|-----------------|---------|-----|
| Creation date | 19th March 2019 | Version | 2.0 |
| Revision date | 28th June 2023 | | |

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

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Substance / mixture

mixture

Number

XSYS0084

Other mixture names

C-REACTIVE PROTEIN HIGH SENSITIVE; CRP-HS

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

Diagnostic reagent for quantitative in vitro determination of C-Reactive Protein in 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

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Web address

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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.

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

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. Aqueous solution of anorganic salts and organic components.

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

Supply fresh air, consult doctor in case of breathing problems develop.

If on skin

Wash with soap and water. If symptoms persist, consult doctor.

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

May cause irritations.

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**

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 mixture

Nitrogen oxides (NO_x), Oxides of phosphorus (PxO_y), Carbon monoxide (CO) and Carbon dioxide (CO₂).

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.

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

Follow the instructions in the Sections 7 and 8. Wear protective clothing. Do not breathe vapors. Avoid skin and eye contact.

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

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of contaminated material as waste according to item 13. Clean contaminated surfaces with an excess of water. Wash clothing and equipment after handling.

6.4. Reference to other sections

See the Section 7, 8 and 13.

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

Observe normal to strict hygiene standards. Handle and open the container with care. Ensure good ventilation/exhaustion at the workplace. Do not inhale aerosols. Avoid prolonged or repeated skin contact. Avoid contact with eyes. 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. Protect from heat and direct sunlight. Store in a cool place.

Storage temperature

min 2 °C, max 8 °C

7.3. Specific end use(s)

The reagent of the kit is designed for in vitro diagnostic use.

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 195/2021 Coll.**

| Substance name (component) | Type | Value | Conversion for ppm | Note |
|--------------------------------|-------|-----------------------|--------------------|--|
| sodium azide (CAS: 26628-22-8) | PEL | 0,1 mg/m ³ | 0,370 | skin penetration is significantly involved during exposure, irritating to mucous membranes (eyes, respiratory system) and skin |
| | NPK-P | 0,3 mg/m ³ | 0,370 | |

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 | |

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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

Keep away from foodstuffs, beverages and food. Do not inhale gases / fumes / aerosols. Avoid close or long term contact with the skin. Avoid contact with the eyes. Wash hands during breaks and at the end of the work.

Eye/face protection

It is not needed.

Skin protection

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

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 | data not available |
| 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 |
| Density and/or relative density | data not available |
| Relative vapour density | data not available |
| Particle characteristics | data not available |

9.2. Other information

| | |
|----------------------|---|
| Evaporation rate | data not available |
| Appearance | Clear liquid |
| Oxidising properties | The product has no oxidizing properties. |
| Explosive properties | The product does not have explosive properties. |

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SECTION 10: Stability and reactivity**10.1. Reactivity**

Stable reactivity until expiry date if stored in recommended conditions.

10.2. Chemical stability

Stable reactivity until expiry date if stored in recommended 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

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**

No toxicological data is available for the mixture.

Acute toxicity

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

| Route of exposure | Parameter | Value | Exposure time | Species | Sex |
|-------------------|------------------|----------------------|---------------|---------|-----|
| Oral | LD ₅₀ | 27 mg/kg bw | | | |
| Inhalation | LC ₅₀ | 54 mg/m ³ | 4 hours | Rat | |

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.

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**

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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

Data not available.

12.3. Bioaccumulative potential

Not available.

12.4. Mobility in soil

Not available.

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

Slightly hazardous for water.

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.

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

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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).

National regulations (Germany)

WGK Water hazard class: nwg - non-hazardous to water

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. |
| 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 |

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

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 29 October 2019. Changes were made in sections 1, 2, 11, 12, 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.