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Section 1. Identification of the substance / mixture and of the company

1.1 Product identifier

CRP test kit, ST 0100

CRP test kit with integrated capillary, ST 0102

hsCRP test kit, ST 0105

Reagent R1 - cuvette

Reagent R2 - cap

1.2 Relevant identified uses of the substance or mixture and uses advised against Identified uses

In-vitro diagnostics; please refer to the product insert.

1.3 Supplier's details

Company name Eurolyser Diagnostica GmbH

Address, P.O. Box

Postcode / Place

Country

Bayernstraße 11a

5020 Salzburg

Österreich

 Telephone
 +43 662 432100

 Facsimile
 +43 662 432100 50

 E-Mail
 sds@eurolyser.com

1.4 Emergency telephone number

Toxicological information-emergency centre +43 1 406 43 43

MO – SU, 0 – 24 h German and English

Section 2. Hazards Identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 (CLP)

Reagent 1 not classified as hazardous
Reagent 2 not classified as hazardous

2.2 Label elements

Reagent 1 has not to be labelled Reagent 2 has not to be labelled



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| Hazard pictograms | not applicable |
|---|----------------|
| Signal words | not applicable |
| Hazard statement(s) in full | not applicable |
| Precautionary statement(s) in full | not applicable |
| Any additional hazardous information (EU) | not applicable |
| Any additional applicable label elements | not applicable |

2.3 Other hazards

No data available.

Section 3. Composition / information on ingredients

3.1 Substance

Not applicable.

3.2 Mixture

Reagent 1 and Reagent 2

The following ingredients are classified as dangerous:

| Substance | Identifier | w.% | Classification in acc. with 1272/2008/EC |
|----------------|--------------------|-------|--|
| Sodium acid | CAS-No. 26628-22-8 | < 0.1 | Acute Tox. 2 H 300 |
| (Reagent 1 and | | | Acute Tox. 1 H 310 |
| Reagent 2) | | | STOT RE2 H 373 |
| | | | Aquatic Chronic 1 H 410 |

For the full text of the H-statements mentioned in this Section, see Section 16.

| Section 4. | First aid measures |
|------------|-----------------------------------|
| 4.1 | Description of first aid measures |
| 4.1.1 | General notes |

Dilutable with water. Remove contaminated clothing.





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4.1.2 Following inhalation

EUROLyser

Supply fresh air. If you feel unwell, consult a doctor. In case of unconscious place in recovery position.

4.1.3 Following skin contact

Rinse skin with soap and water. If symptoms persist, consult a doctor.

4.1.4 Following eye contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

4.1.5 Following ingestion

Give water to drink. Seek medical advice immediately. Induce vomiting.

4.1.6 Self-protection of the first aider

No data available.

4.2 Most important symptoms and effects, both acute and delayed

Eye contact may cause irritations.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5.1 Extinguishing media

5.1.1 Suitable extinguishing media

Product is non-combustible. Extinguishing materials should therefore be selected according to surrounding.

5.1.2 Unsuitable extinguishing media

Not applicable.



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5.2 Special hazards arising from the substance or mixture

The product is non-reactive under normal conditions of use, storage and transport. Fires in the immediate vicinity may cause the development of dangerous vapours.

5.3 Advice for firefighters

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

Preventive skin protection recommended. Use disposable gloves. Do not swallow.

6.1.1 For non-emergency personnel

No data available.

6.1.2 For emergency responders

No data available.

6.2 Environmental precautions

Avoid emissions into soil or water. Retain contaminated water and dispose it in accordance to local regulations.

6.3 Methods and materials for containment and cleaning up

6.3.1 Appropriate containment

Cover drains. Collect, bind and pump off spills. Collect the material for disposal in tightly closed containers.

6.3.2 Clean-up procedures

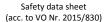
Spillages should be washed with soap and water.

6.3.3 Other information

No further information.

6.4 Reference to other sections

Refer additionally to chapter 7, 8 and 13.





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Section 7. Handling and storage

7.1 Precautions for safe handling

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.

7.2 Conditions for safe storage, including any incompatibilities

Store according to temperature stated on the product label or according to the package insert provided. Avoid direct sunlight and temperature outside the recommended storage conditions.

7.3 Specific end use(s)

No data available.



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Section 8. Exposure controls / personal protection

8.1 Control parameters

| Country | Substance | CAS No. | OEL [mg/m ³] | reference |
|---------|-------------|------------|--------------------------|--------------------|
| EU | Sodium acid | 26628-22-8 | 0,29 | ACGIH Report, 2008 |

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Ensure adequate ventilation.

8.2.2 Personal protective equipment

Avoid skin and eye contact. Wash hands before breaks and immediately after product handling. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the workplace.



8.2.2.1 Eye / face protection

Avoid skin and eye contact. No further measures need to be taken into account.

8.2.2.2 Skin protection

Use appropriate disposal gloves according to EN 374. It is recommended to check the chemical resistance of the protective gloves. Also pay attention to a proper method to strip off the gloves.

8.2.2.3 Respiratory protection

Not relevant.

8.2.2.4 Thermal hazards

Not relevant.

8.2.3 Environmental exposure controls

Avoid emissions into soil or water.



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Section 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

| | <u>Reagent 1</u> | <u>Reagent 2</u> |
|----------------------------------|------------------------------|------------------------------|
| Appearance | | |
| Physical state | Fluidic solution | Fluidic solution |
| Color | Colorless | White suspension |
| Odour | Odourless | Odourless |
| Odour threshold | No data available | No data available |
| Other physical and chemical para | meters | |
| pH-value | No data available | No data available |
| Melting point / freezing point | No data available | No data available |
| Initial boiling point / boiling | No data available | No data available |
| range | | |
| Flash point | Not combustible | Not combustible |
| Evaporation rate | No data available | No data available |
| Flammability (solid, gas) | No data available | No data available |
| Flammability or explosive limits | | |
| Upper limit | No data available | No data available |
| Lower limit | No data available | No data available |
| Vapour pressure | No data available | No data available |
| Vapour density | No data available | No data available |
| Relative density | No data available | No data available |
| Solubility(ies) | | |
| Water solubility | Completely soluble | Completely soluble |
| Partition coefficient | | |
| n-Octanol/water | No data available | No data available |
| Auto-ignition temperature | Product is not self-igniting | Product is not self-igniting |
| Decomposition temperature | No data available | No data available |
| Viscosity | No data available | No data available |
| Explosive properties | Product is not explosive | Product is not explosive |
| Oxidising properties | No data available | No data available |
| | | |

9.2 Other information

No data available.



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Section 10. Stability and Reactivity

10.1 Reactivity

No hazardous reactions for the mixture and the contained substances in dissolved state were observed.

10.2 Chemical stability

Both reagents are stable under normal ambient conditions and at normal storage and handling conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

Avoid direct sunlight, vibration or high temperature.

10.5 Incompatible materials

Strong acids and alkalis

10.6 Hazardous decomposition products

Fires in the immediate vicinity may cause the development of dangerous vapours.

Section 11. Toxicological information

11.1 Information on toxicological effects

11.1.1 Toxicological effects

Reagent 1 and Reagent 2

| Acute toxicity (oral) | No data available |
|--|-------------------|
| Acute toxicity (dermal) | No data available |
| Acute toxicity (inhalative) | No data available |
| Skin corrosion/irritation | No data available |
| Eye damage/irritation | No data available |
| Sensitisation to the respiratory tract | No data available |
| Skin sensitisation | No data available |
| Germ cell mutagenicity/Genotoxicity | No data available |
| Carcinogenicity | No data available |
| Reproductive toxicity | No data available |
| | |



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Effects on or via lactation STOT (single exposure) STOT (repeated exposure) Aspiration hazard No data available No data available No data available No data available

11.1.2 Other information

No data available.

Section 12. Ecological information

12.1 Toxicity

No data available.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

No data available.

12.6 Other adverse effects

General information: Do not allow to enter into ground-water, surface water or drains.

12.7 Other information

No data available.



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Section 13. Disposal considerations

13.1 Waste treatment methods

13.1.1 Product and packaging disposal

Waste disposal must be in accordance with appropriate Federal and local regulations.

13.1.2 Waste treatment-relevant information

Avoid emissions into soil or water. Retain contaminated water and dispose it in accordance to local regulations. Cover drains. Collect, bind and pump off spills.

13.1.3 Sewage disposal-relevant information

Avoid emissions into soil or water.

13.1.4 Other disposal recommendations

No data available

Section 14. Transport information

14.1 UN number

Transportation of the product is not regulated by ADR.

14.2 UN proper shipping name

Not relevant.

14.3 Transport hazard class(es)

Not relevant.

14.4 Packaging group

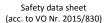
Not relevant.

14.5 Environmental hazards

No. (Not dangerous for the environment according to dangerous goods regulation).

14.6 Special precautions for user

No dangerous good in sense of these transport regulations.





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14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

No data available.

Section 15. Regulatory information

15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture

Reagent 1 and Reagent 2

Classification, labelling and packaging of substances and mixtures (CLP)

VO (EG) Nr. 1272/2008

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

VO (EG) Nr. 2015/830

Regulations of the insurance funds

Federal law on occupational health and safety

BGBl.Nr. 60/2015

15.2 Chemical Safety Assessment

No chemical safety assessment has been carried out for this substance / mixture by the supplier.



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Section 16. Other information

Abbreviation

| ADR | Accord européen relative au transport international des marchandises |
|-------|--|
| | Dangereuses par Route |
| CLP | Classification, Labelling and Packaging |
| OEL | Occupational Exposure Limit |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| STOT | specific target organ toxicity |

Sodium acid

| H 300 | Fatal if swallowed |
|-------|---|
| H 310 | Fatal in contact with skin |
| H 373 | May cause damage to organs through prolonged or repeated exposure |
| H 410 | Very toxic to aquatic life with long-lasting effects |

The information provided in this Safety Data Sheet is provided in the interest of promoting safe handling of the material. While this information is believed to be correct Eurolyser Diagnostica GmbH makes no warranty in respect to any of the information disclosed. Observe all federal, provincial, state and local laws concerning health and pollution.