



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH) and Regulation (EU) No 2020/878

## Creatinine PAP FS Reagent R2

Material number 1 1759 R2

Revision date: 20.12.2022

Version: 9.1

Replaces version: 9.0

Language: en-DE

Date of print: 11.1.2023

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

#### 1.1 Product identifier

Trade name: Creatinine PAP FS Reagent R2

As part of the kits: 1 1759 XX XX XXX  
(The positions X code different packages.)

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

General use: Reagent for in-vitro diagnostics in human samples  
For professional use only.

#### 1.3 Details of the supplier of the safety data sheet

Company name: DiaSys Diagnostic Systems GmbH

Street/POB-No.: Alte Strasse 9

Postal Code, city: DE-65558 Holzheim

WWW: <http://www.diasys.de>

E-mail: [mail@diasys.de](mailto:mail@diasys.de)

Telephone: +49 (0) 6432-9146-0

Telefax: +49 (0) 6432-9146-32

Department responsible for information:

Corporate headquarters, Telephone: +49 (0) 6432-9146-0, Email: [mail@diasys.de](mailto:mail@diasys.de)

#### 1.4 Emergency telephone number

Infraserv, Telephone: +49 (0) 69-305-6418

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

Classification according to EC regulation 1272/2008 (CLP)

This mixture is classified as not hazardous.

#### 2.2 Label elements

##### Labelling (CLP)

Hazard statements: not applicable

Precautionary statements: not applicable

##### Special labelling

EUH210 Safety data sheet available on request.

#### 2.3 Other hazards

No risks worthy of mention.

Endocrine disrupting properties, Results of PBT and vPvB assessment:

No data available

### SECTION 3: Composition/information on ingredients

3.1 Substances: not applicable

#### 3.2 Mixtures

Chemical characterisation: Aqueous solution of inorganic salts and organic compounds.

Hazardous ingredients:

| Identifiers                        | Designation<br>Classification   | Content  |
|------------------------------------|---|----------|
| EC No. 249-954-1<br>CAS 29915-38-6 | 3-(tris(Hydroxymethyl)methylamino)propane-1-sulphonic acid<br>Acute Tox. 4; H302. Acute Tox. 4; H312. | 1 - 10 % |

Full text of H- and EUH-statements: see section 16.

Additional information: Contains Sodium azide (0,95 g/L) as preservative.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

In case of inhalation: Move victim to fresh air. If you feel unwell, seek medical advice.

Following skin contact: Change contaminated clothing. Remove residues with water. In case of skin reactions, consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. In case of troubles or persistent symptoms, consult an ophthalmologist.

After swallowing: Rinse mouth thoroughly with water. Do not induce vomiting without medical advice. Have victim drink large quantities of water, with active charcoal if possible. Seek medical attention. Never give anything by mouth to an unconscious person.

### 4.2 Most important symptoms and effects, both acute and delayed

No data available

### 4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media: Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.

### 5.2 Special hazards arising from the substance or mixture

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

In case of fire may be liberated: Nitrogen oxides (NOx), carbon monoxide and carbon dioxide.

### 5.3 Advice for firefighters

Special protective equipment for firefighters: Wear self-contained breathing apparatus.

Additional information: 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

Avoid contact with skin and eyes. Wear appropriate protective equipment.

### 6.2 Environmental precautions

Do not allow to penetrate into soil, waterbodies or drains.

### 6.3 Methods and material for containment and cleaning up

Soak up with absorbent materials such as sand, siliceous earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance. Wash spill area with plenty of water.

### 6.4 Reference to other sections

Refer additionally to section 8 and 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed. Avoid contact with skin and eyes. Keep all containers, equipment and working place clean. Wear appropriate protective equipment. Wash hands before breaks and after work. Do not eat, drink or smoke when using this product.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers: Keep containers tightly closed and at a temperature between 2 °C and 8 °C. Do not freeze. Protect from light. Keep sterile.

Hints on joint storage: Do not store together with: Acids, alkalis.

Storage class: 12 = Non-combustible liquids

### 7.3 Specific end use(s)

No information available.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

Additional information: Contains no substances with occupational exposure limit values.

### 8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area.

### Personal protection equipment

#### Occupational exposure controls

Respiratory protection: If vapours form, use respiratory protection. Use filter type ABEK according to EN 14387.

Hand protection: Protective gloves according to EN 374. Glove material: Nitrile rubber-Breakthrough time: >480 min. Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection: Tightly sealed goggles according to EN 166.

Body protection: Wear suitable protective clothing.

General protection and hygiene measures: Avoid contact with skin and eyes. Change contaminated clothing. Wash hands before breaks and after work. Do not eat, drink or smoke when using this product.

### Environmental exposure controls

Refer to "6.2 Environmental precautions".

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state at 20 °C and 101.3 kPa: liquid  
Colour: light brown, clear  
Odour: odourless  
Odour threshold: No data available

|   |                        |
|---|------------------------|
| Melting point/freezing point:                 | approx. 0 °C (Water)   |
| Initial boiling point and boiling range:      | approx. 100 °C (Water) |
| Flammability:                                 | No data available      |
| Upper/lower flammability or explosive limits: | No data available      |
| Flash point/flash point range:                | not combustible        |
| Decomposition temperature:                    | No data available      |
| pH:   | at 25 °C: 8,1          |
| Viscosity, kinematic:                         | No data available      |
| Water solubility:                             | completely miscible    |
| Partition coefficient: n-octanol/water:       | No data available      |
| Vapour pressure:                              | No data available      |
| Density:                                      | at 20 °C: 1,003 g/mL   |
| Vapour density:                               | No data available      |
| Particle characteristics:                     | Not applicable         |

### 9.2 Other information

|                            |                   |
|----------------------------|-------------------|
| Explosive properties:      | No data available |
| Oxidizing characteristics: | No data available |
| Auto-ignition temperature: | No data available |
| Evaporation rate:          | No data available |
| Additional information:    | No data available |

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

refer to 10.3

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

No hazardous reactions known.

### 10.4 Conditions to avoid

Protect against heat /sun rays.

### 10.5 Incompatible materials

Strong acids and alkalis

### 10.6 Hazardous decomposition products

No hazardous decomposition products when regulations for storage and handling are observed.

|                        |                   |
|------------------------|-------------------|
| Thermal decomposition: | No data available |
|------------------------|-------------------|

### SECTION 11: Toxicological information

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

Toxicological effects:

- Acute toxicity (oral): Lack of data.
- Acute toxicity (dermal): Lack of data.
- Acute toxicity (inhalative): Lack of data.
- Skin corrosion/irritation: Lack of data.
- Serious eye damage/irritation: Lack of data.
- Sensitisation to the respiratory tract: Lack of data.
- Skin sensitisation: Lack of data.
- Germ cell mutagenicity/Genotoxicity: Lack of data.
- Carcinogenicity: Lack of data.
- Reproductive toxicity: Lack of data.
- Effects on or via lactation: Lack of data.
- Specific target organ toxicity (single exposure): Lack of data.
- Specific target organ toxicity (repeated exposure): Lack of data.
- Aspiration hazard: Lack of data.

#### 11.2 Information on other hazards

Endocrine disrupting properties: No data available

Other information:

- Contains Sodium azide (0,95 g/L):
- After resorption of toxic quantities: Headache, dizziness, nausea, cough, vomiting, spasms, breathing paralysis, CNS disorders, low blood pressure, cardiovascular failure, unconsciousness, collapse.
- Information about 3-(tris(Hydroxymethyl)methylamino)propane-1-sulphonic acid
- Acute oral toxicity: 500 mg/kg
- Acute dermal toxicity: 1100 mg/kg
- Source: Data obtained by expert judgement.

### SECTION 12: Ecological information

#### 12.1 Toxicity

Water Hazard Class: 1 = slightly hazardous to water

#### 12.2 Persistence and degradability

Further details: No data available

#### 12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water:  
No data available

#### 12.4 Mobility in soil

No data available

#### 12.5 Results of PBT and vPvB assessment

No data available

#### 12.6 Endocrine disrupting properties

No data available

#### 12.7 Other adverse effects

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



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### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

##### Product

Waste key number: 16 05 06\* = Laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals.

\* = Evidence for disposal must be provided.

Recommendation: Special waste. Dispose of waste according to applicable legislation.

##### Package

Waste key number: 15 01 02 = Plastic packaging

Recommendation: Dispose of waste according to applicable legislation.

Non-contaminated packages may be recycled.

### SECTION 14: Transport information

#### 14.1 UN number or ID number

ADR/RID, ADN, IMDG, IATA-DGR:

not applicable

#### 14.2 UN proper shipping name

ADR/RID, ADN, IMDG, IATA-DGR:

Not restricted

#### 14.3 Transport hazard class(es)

ADR/RID, ADN, IMDG, IATA-DGR:

not applicable

#### 14.4 Packing group

ADR/RID, ADN, IMDG, IATA-DGR:

not applicable

#### 14.5 Environmental hazards

Dangerous for the environment: Substance/mixture is not environmentally hazardous according to the criteria of the UN model regulations.

Marine pollutant - IMDG:

no

#### 14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

#### 14.7 Maritime transport in bulk according to IMO instruments

No data available

### SECTION 15: Regulatory information

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

##### National regulations - Germany

Storage class: 12 = Non-combustible liquids

Water Hazard Class: 1 = slightly hazardous to water

Further regulations, limitations and legal requirements:

No data available

##### National regulations - EC member states

Further regulations, limitations and legal requirements:

No data available

### 15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.

## SECTION 16: Other information

Wording of the H-phrases under paragraph 2 and 3:

H302 = Harmful if swallowed.

H312 = Harmful in contact with skin.

EUH210 = Safety data sheet available on request.

Reason of change: General revision

Date of first version: 7.3.2008

Department issuing data sheet: see section 1: Department responsible for information

Abbreviations and acronyms:

- Acute Tox.: Acute toxicity
- ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- AS/NZS: Australian Standards/New Zealand Standards
- CAS: Chemical Abstracts Service
- CFR: Code of Federal Regulations
- CLP: Classification, Labelling and Packaging
- CNS: Central Nervous System
- DMEL: Derived minimal effect level
- DNEL: Derived no-effect level
- EC: European Community
- EN: European Standard
- EQ: Excepted quantities
- EU: European Union
- IATA: International Air Transport Association
- IATA-DGR: International Air Transport Association – Dangerous Goods Regulations
- IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
- IMDG Code: International Maritime Dangerous Goods Code
- MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
- OSHA: Occupational Safety and Health Administration
- PBT: Persistent, bioaccumulative and toxic
- PNEC: Predicted no-effect concentration
- RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
- TRGS: Technical Rules for Hazardous Substances
- vPvB: Very persistent and very bioaccumulative

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.