

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

### 1.1 Product identifier

Trade name: Creatinine FS Reagent R1

As part of the kits: 1 1711 XX XX XXX  
(The positions X code different packages.)

UFI: RG10-S0GU-K000-2X04

### 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)**

Met. Corr. 1; H290 May be corrosive to metals.

Skin Irrit. 2; H315 Causes skin irritation.

Eye Irrit. 2; H319 Causes serious eye irritation.

### 2.2 Label elements

#### Labelling (CLP)



Signal word:

**Warning**

Hazard statements:

H290

May be corrosive to metals.

H315

Causes skin irritation.

H319

Causes serious eye irritation.

Precautionary statements:	P234	Keep only in original packaging.
	P264	Wash hands and face thoroughly after handling.
	P280	Wear protective gloves/protective clothing/eye protection.
	P302+P352	IF ON SKIN: Wash with plenty of water/soap.
	P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P332+P313	If skin irritation occurs: Get medical advice/attention.
	P337+P313	If eye irritation persists: Get medical advice/attention.
	P390	Absorb spillage to prevent material damage.

### 2.3 Other hazards

A corrosive effect cannot be ruled out because of the pH value.

Special danger of slipping by leaking/spilling product.

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

Hazardous ingredients:

Identifiers	Designation Classification	Content
REACH 01-2119457892-27-xxxx EC No. 215-185-5 CAS 1310-73-2	Sodium hydroxide Met. Corr. 1; H290. Skin Corr. 1A; H314.  Specific concentration limits (SCL): Skin Corr. 1A; H314: $C \geq 5\%$ / Skin Corr. 1B; H314: $2\% \leq C < 5\%$ / Skin Irrit. 2; H315: $0,5\% \leq C < 2\%$ / Eye Irrit. 2; H319: $0,5\% \leq C < 2\%$	0,5 - 1,5 %

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

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

General information:	First aider: Pay attention to self-protection! If medical advice is needed, have product container or label at hand.
In case of inhalation:	Move victim to fresh air, put at rest and loosen restrictive clothing. Seek medical attention.
Following skin contact:	Take off immediately all contaminated clothing and wash it before reuse. After contact with skin, wash immediately with plenty of water. Cover with sterile dressing material to protect against infection. Seek medical attention.
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. Subsequently seek the immediate attention of an ophthalmologist.
After swallowing:	Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person. Do not induce vomiting. Risk of perforation! Do not try to neutralize. Immediately get medical attention.

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

Causes skin irritation. Causes serious eye irritation.

A corrosive effect cannot be ruled out because of the pH value. May cause respiratory irritation.

In case of ingestion: Irritant up to corrosive.

#### 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 the event of a fire, the following may be produced when the water evaporates: Sodium compounds, carbon monoxide and carbon dioxide.

#### 5.3 Advice for firefighters

Special protective equipment for firefighters:

In case of surrounding fires: Wear a self-contained breathing apparatus and chemical protective clothing.

### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes. Provide adequate ventilation. Wear appropriate protective equipment. Do not breathe vapours. Keep unprotected people away. Take off immediately all contaminated clothing and wash it before reuse.

#### 6.2 Environmental precautions

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

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

Dilute with plenty of water.  
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. Final cleaning.  
Special danger of slipping by leaking/spilling product.

#### 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. Do not breathe vapours. Avoid contact with skin and eyes. Wear appropriate protective equipment. Take off immediately all contaminated clothing and wash it before reuse. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Have eye wash bottle or eye rinse ready at work place.

#### 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 25 °C.  
Protect from light. Do not freeze. Keep away from heat. Store containers in upright position.  
Unsuitable materials: Light metals

Hints on joint storage:

Do not store together with ammonium compounds or acids.  
Keep away from food, drink and animal feedingstuffs.

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 adequate ventilation, and local exhaust as needed.

### Personal protection equipment

#### Occupational exposure controls

Respiratory protection: Use a breathing protection against vapours/aerosol.  
Use filter type (A-P2/P3) according to EN 14387.

Hand protection: Protective gloves according to EN 374.  
Glove material: Nitrile rubber-Layer thickness: 0,11 mm.  
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:  
Do not breathe vapours. Do not get in eyes, on skin, or on clothing. Take off immediately all contaminated clothing and wash it before reuse. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Have eye wash bottle or eye rinse ready at work place.

### 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:	colourless, clear
Odour:	no characteristic odour
Odour threshold:	No data available
Melting point/freezing point:	approx. 0 °C
Initial boiling point and boiling range:	approx. 100 °C
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: approx. 13,0
Viscosity, kinematic:	No data available
Water solubility:	at 20 °C: completely miscible
Partition coefficient: n-octanol/water:	No data available
Vapour pressure:	No data available
Density:	at 20 °C: 1,0075 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

May be corrosive to metals.

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

Reacts with ammonium compounds: Formation of ammonia.

Reacts with light metals: Formation of hydrogen.

### 10.4 Conditions to avoid

Protect from frost, heat and sunlight.

### 10.5 Incompatible materials

Acids, ammonium compounds

### 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:	The statements are derived from the properties of the single components. No toxicological data is available for the product as such.
	Acute toxicity (oral): Lack of data.
	Acute toxicity (dermal): Lack of data.
	Acute toxicity (inhalative): Lack of data.
	Skin corrosion/irritation: Skin Irrit. 2; H315 = Causes skin irritation.
	Serious eye damage/irritation: Eye Irrit. 2; H319 = Causes serious eye irritation.
	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

**Symptoms**

A corrosive effect cannot be ruled out because of the pH value. May cause respiratory irritation.

In case of ingestion: Irritant up to corrosive.

After eye contact: Upon direct contact with eyes may cause burning, tearing, redness.

**SECTION 12: Ecological information****12.1 Toxicity**

Aquatic toxicity: Harmful effects on water organisms by modification of pH-value.

Water Hazard Class: 1 = slightly hazardous to water

**12.2 Persistence and degradability**

Further details: Methods for the determination of biodegradability are not applicable to inorganic substances.

**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.

**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:  
UN 1824

**14.2 UN proper shipping name**

ADR/RID, ADN, IMDG, IATA-DGR:  
UN 1824, SODIUM HYDROXIDE SOLUTION

### 14.3 Transport hazard class(es)

ADR/RID, ADN: Class 8, Code: C5  
IMDG: Class 8, Subrisk -  
IATA-DGR: Class 8



### 14.4 Packing group

ADR/RID: III

### 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

#### Land transport (ADR/RID)

Warning board: ADR/RID: Kemmler-number 80, UN number UN 1824  
Hazard label: 8  
Limited quantities: 5 L  
EQ: E1  
Package - Instructions: P001 IBC03 LP01 R001  
Special provisions for packing together: MP19  
Portable tanks - Instructions: T4  
Portable tanks - Special Provisions: TP1  
Tank coding: L4BN  
Tunnel restriction code: E

#### Inland waterway craft (ADN)

Hazard label: 8  
Limited quantities: 5 L  
EQ: E1  
Transport permitted: T  
Equipment necessary: PP - EP

#### Sea transport (IMDG)

EmS: F-A, S-B  
Special Provisions: 223  
Limited quantities: 5 L  
Excepted quantities: E1  
Package - Instructions: P001, LP01  
Package - Provisions: -  
IBC - Instructions: IBC03  
IBC - Provisions: -  
Tank instructions - IMO: -  
Tank instructions - UN: T4  
Tank instructions - Provisions: TP1  
Stowage and handling: Category A.  
Segregation: SG35  
Properties and observations: Colourless liquid. Corrosive to aluminium, zinc and tin. Reacts with ammonium salts, evolving ammonia gas. Causes burns to skin, eyes and mucous membranes. Reacts violently with acids.  
Segregation group: 18



# SAFETY DATA SHEET

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

## Creatinine FS Reagent R1

Material number 1 1711 R1

Revision date: 20.12.2022

Version: 23.1

Replaces version: 23.0

Language: en-DE

Date of print: 11.1.2023

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### Air transport (IATA)

Hazard label:	Corrosive
Excepted Quantity Code:	E1
Passenger and Cargo Aircraft: Ltd.Qty.:	Pack.Instr. Y841 - Max. Net Qty/Pkg. 1 L
Passenger and Cargo Aircraft:	Pack.Instr. 852 - Max. Net Qty/Pkg. 5 L
Cargo Aircraft only:	Pack.Instr. 856 - Max. Net Qty/Pkg. 60 L
Special Provisions:	A3 A803
Emergency Response Guide-Code (ERG):	8L

### 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  
Information on working limitations:  
Observe employment restrictions for young people.  
Further regulations, limitations and legal requirements:  
No data available

#### National regulations - EC member states

Further regulations, limitations and legal requirements:  
Use restriction according to REACH annex XVII, no.: 3

### 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:

H290 = May be corrosive to metals.  
H314 = Causes severe skin burns and eye damage.  
H315 = Causes skin irritation.  
H319 = Causes serious eye irritation.

Reason of change: General revision

Date of first version: 7.11.2006

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



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Abbreviations and acronyms:

- 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
- DMEL: Derived minimal effect level
- DNEL: Derived no-effect level
- EC: European Community
- EN: European Standard
- EQ: Excepted quantities
- EU: European Union
- Eye Irrit.: Eye irritation
- 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
- Met. Corr.: Corrosive to metals
- OSHA: Occupational Safety and Health Administration
- PBT: Persistent, bioaccumulative and toxic
- PNEC: Predicted no-effect concentration
- REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
- RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
- Skin Corr.: Skin corrosion
- Skin Irrit.: Skin irritation
- TRGS: Technical Rules for Hazardous Substances
- UN: United Nations
- 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.