

Creatinine FS Reagent R1

Material number 1 1711 R1

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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: 65558 Holzheim
WWW: <http://www.diasys.de>
E-mail: 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

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.

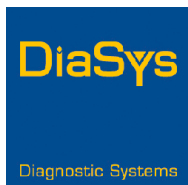
2.2 Label elements

Labelling (CLP)



Signal word: **Warning**

Hazard statements:	H290	May be corrosive to metals.
	H315	Causes skin irritation.
	H319	Causes serious eye irritation.



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according to Regulation (EC) No. 1907/2006 (REACH) and Regulation (EU) No. 2015/830

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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.

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:

Ingredient	Designation	Content	Classification
REACH 01-2119457892-27-xxxx EC No. 215-185-5 CAS 1310-73-2	Sodium hydroxide	0.5 - 1.5 %	Met. Corr. 1; H290. Skin Corr. 1A; H314.

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.

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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.

Additional information:

Hazchem-Code: 2R

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.

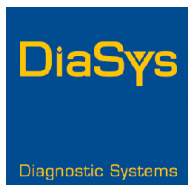
Soak up with absorbent materials such as sand, siliceous earth, acid- or universal binder.

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.



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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.

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
1310-73-2	Sodium hydroxide	Great Britain: WEL-STEL	2 mg/m ³
		Ireland: 15 minutes	2 mg/m ³

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".

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance:	Physical state at 20 °C and 101.3 kPa: liquid Colour: colourless, clear
Odour:	no characteristic odour
Odour threshold:	No data available
pH:	at 25 °C: approx. 13.0
Melting point/freezing point:	approx. 0 °C
Initial boiling point and boiling range:	approx. 100 °C
Flash point/flash point range:	not combustible
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	No data available
Vapour pressure:	No data available
Vapour density:	No data available
Density:	at 20 °C: 1.0075 g/mL
Water solubility:	at 20 °C: completely miscible
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity, kinematic:	No data available
Explosive properties:	No data available
Oxidizing characteristics:	No data available

9.2 Other information

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

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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 toxicological effects

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.

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.

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

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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.

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

ADR/RID, IMDG, IATA-DGR:
UN 1824

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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



14.4 Packing group

ADR/RID, IMDG, IATA-DGR:
III

14.5 Environmental hazards

Marine pollutant: no

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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

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

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

No data available



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SECTION 15: Regulatory information

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

National regulations - Great Britain

Hazchem-Code: 2R
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

Further 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.

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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
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
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
TRGS: Technical Rules for Hazardous Substances
UN: United Nations
vPvB: Very persistent and very bioaccumulative

Reason of change: Changes in section 1: Product Identification

Date of first version: 7/11/2006

Department issuing data sheet

Contact person: see section 1: Department responsible for information

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.