

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

1.1 Product identifier

Trade name: Urea CT FS Reagent R2

As part of the kits: 1 3115 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

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.

Precautionary statements:

P234 Keep only in original packaging.
P280 Wear protective gloves/protective clothing/eye protection.
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.

2.3 Other hazards

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

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 - 2 %

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

SECTION 4: First aid measures

4.1 Description of first aid measures

In case of inhalation:	Move victim to fresh air, put at rest and loosen restrictive clothing. Seek medical aid in case of troubles.
Following skin contact:	Take off 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! 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.

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: Chlorine, sodium compounds, phosphorus oxides.

5.3 Advice for firefighters

Special protective equipment for firefighters:

In case of surrounding fires: Wear self-contained breathing apparatus.

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.

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.

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:

Avoid contact with skin and eyes. Provide adequate ventilation. Wear appropriate protective equipment. Wash hands before breaks and after work. Have eye wash bottle or eye rinse ready at work place. Take off contaminated clothing and wash it before reuse.

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. Protect from light.

Unsuitable materials: Aluminium, tin, zinc.

Hints on joint storage:

Do not store together with ammonium compounds or acids.

Storage class:

8B = Non-combustible corrosive substances

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-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:

Take off contaminated clothing and wash it before reuse. Avoid contact with skin and eyes.

Wash hands before breaks and after work. 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:	weak like chlorine
Odour threshold:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
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: 12,8 g/mL
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: 1,0113 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 against heat /sun rays.

10.5 Incompatible materials

Acids

10.6 Hazardous decomposition products

No decomposition when used properly.

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.

In case of longer contact, danger of serious eye damage.

If swallowed, may cause irritation to the mucous membranes.

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: 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.

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

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: 8B = Non-combustible corrosive substances
 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: 11.1.2007

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

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.