

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

### 1.1 Product identifier

Trade name: Total protein FS Reagent R2

As part of the kits: 1 2311 XX XX XXX  
(The positions X code different packages.)

UFI: J520-U011-000Y-CNNN

### 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](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.
STOT RE 2; H373	May cause damage to organs through prolonged or repeated exposure.
Aquatic Chronic 3; H412	Harmful to aquatic life with long lasting effects.

### 2.2 Label elements

#### Labelling (CLP)



Signal word:

**Warning**

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Hazard statements: H290 May be corrosive to metals.  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H373 May cause damage to organs through prolonged or repeated exposure.  
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements: P234 Keep only in original packaging.  
P273 Avoid release to the environment.  
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.  
P314 Get medical advice/attention if you feel unwell.

### Special labelling

Text for labelling: Contains Potassium iodide.

### 2.3 Other hazards

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

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
EC No. 215-185-5 CAS 1310-73-2	Sodium hydroxide	0.5 - 2 %	Met. Corr. 1; H290. Skin Corr. 1A; H314.
REACH 01-2119966161-40-xxxx EC No. 231-659-4 CAS 7681-11-0	Potassium iodide	< 2 %	STOT RE 1; H372.
EC No. 231-847-6 CAS 7758-99-8	Copper sulphate-5-hydrate	< 1 %	Acute Tox. 4; H302. Eye Dam. 1; H318. Aquatic Acute 1; H400 (M-factor = 10). Aquatic Chronic 1; H410 (M-factor = 1).

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.

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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 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:	Never give anything by mouth to an unconscious person. Rinse mouth immediately and drink plenty of water. Do not induce vomiting. Risk of perforation! Do not try to neutralize. Seek medical attention.

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

May cause damage to organs through prolonged or repeated exposure. 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, copper oxide, hydrogen iodide, sulphur oxides, 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. Take off immediately all contaminated clothing and wash it before reuse.

Wear appropriate protective equipment. Provide adequate ventilation. Do not breathe vapours. Keep unprotected people away.

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### 6.2 Environmental precautions

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

If necessary notify appropriate authorities.

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

Absorb spillage to prevent material damage. 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.

Never return spills in original containers for re-use.

### 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. Take off immediately all contaminated clothing and wash it before reuse. Wear appropriate protective equipment. 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. Keep away from heat. Store containers in upright position.

Unsuitable materials: Metals, 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.

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**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 Ireland: 15 minutes	2 mg/m <sup>3</sup> 2 mg/m <sup>3</sup>
7758-99-8	Copper sulphate-5-hydrate	Great Britain: WEL-STEL  Great Britain: WEL-TWA Great Britain: WEL-TWA  Ireland: 8 hours Ireland: 8 hours	2 mg/m <sup>3</sup> (Dusts and mist calculated as Cu) 0.2 mg/m <sup>3</sup> (Smoke) 1 mg/m <sup>3</sup> (Dusts and mist calculated as Cu) 0.2 mg/m <sup>3</sup> (Smoke) 1 mg/m <sup>3</sup> (Dusts and mist calculated as Cu)

**8.2 Exposure controls**

When aerosols and vapours form: Withdraw by suction.

**Personal protection equipment**

**Occupational exposure controls**

- Respiratory protection: Respiratory protection must be worn whenever the WEL levels have been exceeded. Use filter type (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. Have eye wash bottle or eye rinse ready at work place. Wash hands before breaks and after work.

**Environmental exposure controls**

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

**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: blue, clear
- Odour: no characteristic odour
- Odour threshold: No data available

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pH:	at 25 °C: 13.27
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
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: 1.0454 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 violently with metals and light metals. Formation of hydrogen!

### 10.4 Conditions to avoid

Protect from frost, heat and sunlight.

### 10.5 Incompatible materials

Acids

### 10.6 Hazardous decomposition products

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

Thermal decomposition: No data available

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### 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): Based on available data, the classification criteria are not met.  
ATEmix (calculated): ATE > 5000 mg/kg

Acute toxicity (dermal): Based on available data, the classification criteria are not met.  
ATEmix (calculated): ATE > 5000 mg/kg

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): STOT RE 2; H373 = May cause damage to organs through prolonged or repeated exposure.

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.

### SECTION 12: Ecological information

#### 12.1 Toxicity

Aquatic toxicity: Harmful to aquatic life with long lasting effects.  
Harmful effects on water organisms by modification of pH-value.

Information about Copper sulphate anhydrous:  
Daphnia toxicity:  
EC50 Daphnia magna (Big water flea): 0.02 mg/L/48h  
Fish toxicity:  
LC50 Oncorhynchus mykiss: 0.11 mg/L/96h

#### 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

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### 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.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

#### Product

Waste key number: 06 03 13\* = Solid salts and solutions containing heavy metals.  
\* = 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





# SAFETY DATA SHEET

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

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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)

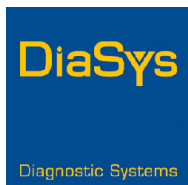
EmS: F-A, S-B  
Special Provisions: 223  
Limited quantities: 5 L  
Excepted quantities: E1  
Package - Instructions: P001, LP01  
Package - Provisions: -  
IBC - Instructions: IBC03  
IBC - Provisions: -  
Tank instructions - IMO: -  
Tank instructions - UN: T4  
Tank instructions - Provisions: TP1  
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.
- H302 = Harmful if swallowed.
- H314 = Causes severe skin burns and eye damage.
- H315 = Causes skin irritation.
- H318 = Causes serious eye damage.
- H319 = Causes serious eye irritation.
- H372 = Causes damage to organs through prolonged or repeated exposure.
- H373 = May cause damage to organs through prolonged or repeated exposure.
- H400 = Very toxic to aquatic life.
- H410 = Very toxic to aquatic life with long lasting effects.
- H412 = Harmful to aquatic life with long lasting effects.



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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  
ATE: Acute toxicity estimate  
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  
EC50: Effective Concentration 50%  
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  
LC50: Median lethal concentration  
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships  
M-factor: Multiplication factor  
OEL: Occupational Exposure Limit Value  
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  
STOT RE: Specific target organ toxicity - repeated exposure  
TLV: Threshold Limit Value  
TRGS: Technical Rules for Hazardous Substances  
UN: United Nations  
vPvB: Very persistent and very bioaccumulative  
WEL: Workplace Exposure Limit

Reason of change: Changes in section 1: Product Identification

Date of first version: 30/11/2006

### 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.