

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: 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.
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

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.

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
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 %
REACH 01-2119966161-40-xxxx EC No. 231-659-4 CAS 7681-11-0	Potassium iodide STOT RE 1; H372.	< 2 %
EC No. 231-847-6 CAS 7758-99-8	Copper sulphate-5-hydrate Acute Tox. 4; H302. Eye Dam. 1; H318. Aquatic Acute 1; H400. Aquatic Chronic 1; H410. Acute toxicity estimate (ATE): Oral: 481 mg/kg bw. M-factors: Aquatic Acute 1: M = 10. Aquatic Chronic 1: M = 1.	< 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.

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.

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.

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.

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

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
7758-99-8	Copper sulphate-5-hydrate	Germany: DFG Kurzzeit	0,02 mg/m ³ (respirable fraction)
		Germany: DFG Langzeit	0,01 mg/m ³ (respirable fraction)

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

Physical state at 20 °C and 101.3 kPa	liquid
Colour:	blue, clear
Odour:	no characteristic odour
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: 13,3
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: 1,0454 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 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 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): 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.

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.

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

Water Hazard Class: 2 = obviously 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: 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 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:	12 = Non-combustible liquids
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Water Hazard Class: 2 = obviously hazardous to water

Information on working limitations:

Observe employment restrictions for young people.

Observe employment restrictions for expectant or nursing mothers.

Further regulations, limitations and legal requirements:

The product is not subject to the Chemicals Prohibition Ordinance (ChemVerbotsV).

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.

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.

Reason of change: General revision

Date of first version: 30.11.2006

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

SAFETY DATA SHEET

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

Total protein FS Reagent R2

Material number 1 2311 R2

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Version: 27.1

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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
- Aquatic Acute: Hazardous to the aquatic environment - acute
- Aquatic Chronic: Hazardous to the aquatic environment - chronic
- AS/NZS: Australian Standards/New Zealand Standards
- ATE: Acute toxicity estimate
- Bw: Body weight
- 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
- Eye Dam.: Eye damage
- 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
- LC50: Median lethal concentration
- MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
- Met. Corr.: Corrosive to metals
- 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
- Skin Corr.: Skin corrosion
- Skin Irrit.: Skin irritation
- 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

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.