

EU SAFETY DATA SHEET

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

Total Protein R2 - Material number: 01 00042**1. Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

Name of product: Total Protein Reagent R2
as part of the kits: 01 00042 XX XX XXXX
(The positions X code different packages.)

1.2 Relevant identified uses of the substance or mixture and uses advised against

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: DiaSystem Scandinavia AB
Street/POB-No.: Datorgatan 3
State/city/postal code: 561 33 Jönköping
Sweden
World Wide Web: <http://www.diasystem.se>
Email: info@diasystem.se
Telephone: +46 (0) 36 12 62 20
Telefax: +46 (0) 36 18 77 30
Dept. responsible for information:
DiaSystem, Telephone: +46 (0)36 126220

1.4 Emergency telephone number

Giftinformationscentralen, Telephone +46 112

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.
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.
H412 Harmful to aquatic life with long lasting effects

Precautionary statements:

P234 Keep only in original packaging.
P264 Wash hands and face thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338IF 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

Results of PBT and vPvB assessment:

No data available

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3. Composition/information on ingredients

3.1 Substances: not applicable

3.2 Mixtures

Chemical characterization: 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 - 2 %	Met. Corr. 1; H290. Skin Corr. 1A; H314.
EC No. 231-659-4 CAS 7681-11-0	Potassium iodide	< 2 %	Acute Tox. 4; H302. Skin Irrit. 2; H315. Eye Irrit. 2; H319.
EC No. 231-847-6 CAS 7758-99-8	Copper sulphate-5hydrate	< 1 %	Acute Tox. 4; H302. Skin Irrit. 2; H315. Eye Irrit. 2; H319. Aquatic Acute 1; H400. Aquatic Chronic 1; H410.

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

Additional information: Information about Copper sulphate-5-hydrate: M-factor acute =1

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. 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

Causes skin irritation.
Causes serious eye irritation.
In case of ingestion: Irritant up to corrosive.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

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 self-contained breathing apparatus

Additional information:

Hazchem-Code: 2R

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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. Wear appropriate protective equipment. Provide adequate ventilation. Do not breathe vapours.

6.2 Environmental precautions

Do not allow to penetrate into soil, waterbodies 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.

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. Wear appropriate protective equipment. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Provide a conveniently located eye rinse station.

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.

8. Exposure controls / Personal protection equipment**8.1 Control parameters**

Occupational exposure limit values

Ingredient	Designation	Type	Limit value
1310-73-2	Sodium hydroxide	Great Britain: WEL-STEL 2 mg/m ³ Ireland: 15 minutes	2 mg/m ³ 2 mg/m ³
7758-99-8	Copper sulphate-5-hydrate	Great Britain: WEL-STEL Great Britain: WEL-TWA Great Britain: WEL-TWA Ireland: 15 minutes Ireland: 8 hours Ireland: 8 hours	2 mg/m ³ (Dusts and mist calculated as Cu) 2 mg/m ³ (Smoke) 1 mg/m ³ (Dusts and mist calculated as Cu) 2 mg/m ³ (Dusts and mist calculated as Cu) 0.2 mg/m ³ (Smoke) 1 mg/m ³ (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. Particulates filter (P2/P3) according to EN 143.

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:

Lab coat

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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. Wash hands before breaks and after work. Provide a conveniently located eye rinse station.

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:	odourless
Odour threshold:	No data available
pH value:	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

10. Stability and reactivity**10.1 Reactivity**

May be corrosive to metals.
Reacts violently with metals and light metals. Formation of hydrogen!

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Reacts with ammonium compounds: Formation of ammonia.

10.4 Conditions to avoid

Keep away from heat.

10.5 Incompatible materials

Acids

10.6 Hazardous decomposition products

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

Thermal decomposition:

No data available

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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.

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

12. Ecological information**12.1 Toxicity**

Further details: Harmful to aquatic life with long lasting effects.
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

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

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. Waste disposal according to official state regulations.

Contaminated packaging

Waste key number 15 01 02 = Plastic packaging.

Recommendation: Dispose of waste according to applicable legislation.
Non-contaminated packages may be recycled.

14.1 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

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Total Protein R2 - Material number: 01 00042**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

14.6 Special precautions for user

Warning board: ADR/RID: Kemmler-number 80, UN number UN 1824
 Hazard label: 8
 Limited quantities: 5 L
 EQ: E1
 Contaminated packaging - Instructions: P001 IBC03 LP01 R001
 Special provisions for packing together: MP19
 Portable tanks - Instructions: T7
 Portable tanks - Special provisions: TP1 TP28
 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
 Contaminated packaging - Instructions: P001, LP01
 Contaminated packaging - 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

15. Other information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****National regulations - Great Britain**

Hazchem-Code: 2R

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No data available

15.2 Chemical Safety Assessment

For this substance a chemical safety assessment is not required.

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.

H319 = Causes serious eye irritation.

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 (Regulation (EU) No 2015/830)

Date of first version: 2011-07-01

Department issuing data sheet

Contact person: see section 1: Dept. responsible for information

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations). 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.