

## 1: Identification

- **Product identifier**
- **Trade name:** **TOTAL PROTEIN REAGENT**
- **Article number:** PROB-5XXX / PROB-0850R
- **Synonyms** TOTAL PROTEIN PLUS R / TOTAL PROTEIN ENVOY R.
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture**  
Reagent for IN VITRO diagnostic
- **Product included in kit(s) :**  
- Kit composed of one reagent : PROB-0250 / 55425.
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
ELITech Clinical Systems SAS  
Zone Industrielle  
61500 Sées • France  
Tel : +33 (0)2 33 81 21 00  
Fax : +33 (0)2 33 28 77 51  
www.elitechgroup.com  
MSDS.ECS-SAS@elitechgroup.com
- **Information department:** Product safety department
- **Emergency telephone number:** Contact your distributor or poison control center in your country.

## 2: Hazard(s) identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS05

Met. Corr.1 H290 May be corrosive to metals.



GHS07

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.

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** The product is classified and labeled according to the CLP regulation.
- **Hazard pictograms**



GHS05

- **Signal word** Warning
- **Hazard statements**  
May be corrosive to metals.  
Causes skin irritation.  
Causes serious eye irritation.  
Harmful to aquatic life with long lasting effects.
- **Precautionary statements**  
Wear protective gloves/protective clothing/eye protection/face protection.  
Avoid release to the environment.  
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
If eye irritation persists: Get medical advice/attention.  
Absorb spillage to prevent material damage.

## 3: Composition/information on ingredients

- **Chemical characterization:** Mixtures
- **Description:**  
Mixture of substances.  
Aqueous solution.

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· **Dangerous components:**

CAS NO.	Description	%
1310-73-2	sodium hydroxide ⚠ Met. Corr. 1, H290; Skin Corr. 1A, H314	≤ 2.5%
7758-99-8	copper(II) sulfate pentahydrate ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410; ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319	< 0.5%

## 4: First-aid measures

· **Description of first aid measures**

· **General information:**

Take off contaminated clothing and wash it before reuse.  
Show this safety data sheet to the doctor in attendance.

· **After inhalation:**

Supply fresh air.  
Move out of dangerous area.  
If required, provide artificial respiration.  
If symptoms appear, seek medical advice.

· **After skin contact:**

Take off contaminated clothing and wash before reuse.  
Immediately wash with water and soap and rinse thoroughly.  
If symptoms appear, seek medical advice.

· **After eye contact:**

Protect unharmed eye.  
Remove contact lenses, if present and easy to do.  
Rinse opened eye for several minutes under running water. If symptoms appear, seek medical advice.

· **After swallowing:**

Never give anything by mouth to an unconscious person.  
Rinse out mouth.  
Do not induce vomiting.  
Seek advice from a doctor or a poison control center.

· **Information for doctor:**

- *Most important symptoms and effects, both acute and delayed*
- A corrosive effect cannot be ruled out because of the pH value.
- Skin irritation
- Eye irritation
- *Indication of any immediate medical attention and special treatment needed* Data not available

## 5: Fire-fighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:**

CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.  
Use fire fighting measures that suit the environment.

· **Special hazards arising from the substance or mixture**

Carbon oxides (CO<sub>x</sub>)  
Sodium oxides.

· **Advice for firefighters**

- **Protective equipment:** As in any fire, wear a respiratory protective device, and full protective gear.

## 6: Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**

Wear protective equipment. Keep unprotected persons away.  
Take off contaminated clothing and wash before reuse.  
Ensure adequate ventilation  
Avoid physical contact with material.  
Avoid formation of gas/mist/vapours.  
Avoid breathing gas/mist/vapours.

· **Environmental precautions:** Prevent seepage into sewage system, workpits and cellars.

· **Methods and material for containment and cleaning up:**

Absorb spillage to prevent material damage.  
Absorb with liquid-binding material (sand, diatomite, universal binders, sawdust).  
Send for recovery or disposal in suitable receptacles.  
Clean the affected area carefully.

· **Reference to other sections**

See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

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## 7: Handling and storage

- **Handling:**
- **Precautions for safe handling**
  - Ensure good ventilation/exhaustion at the workplace.
  - Open and handle receptacle with care.
  - Take off contaminated clothing and wash before reuse.
  - Avoid physical contact with material.
  - Avoid formation of gas/mist/vapours.
  - Avoid breathing gas/mist/vapours.
  - Observe the warnings on the label.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
  - **Requirements to be met by storerooms and receptacles:**
    - Store in a cool location.
    - May be corrosive to metals.
    - Unsuitable material for receptacle: metals.
    - Keep only in original container.
  - **Information about storage in one common storage facility:** Store away from incompatible materials (see section 10).
  - **Further information about storage conditions:**
    - Store receptacle in a well ventilated area.
    - Keep receptacle tightly sealed.
    - Protect the product from light. Avoid exposure to heat.
  - **Recommended storage temperature:** 2-25 °C
- **Specific end use(s)** Data not available

## 8: Exposure controls/personal protection

- **Additional information about design of technical systems:** Eyewash fountain and safety shower in the area of storage and use.
- **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

### 1310-73-2 sodium hydroxide (≤ 2.5%)

PEL (USA)	Long-term value: 2 mg/m <sup>3</sup>
REL (USA)	Ceiling limit value: 2 mg/m <sup>3</sup>
TLV (USA)	Ceiling limit value: 2 mg/m <sup>3</sup>

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
  - The usual precautionary measures for handling chemicals should be followed.
  - Wash hands before breaks and at the end of work.
  - Take off contaminated clothing and wash before reuse.
  - Avoid physical contact with material.
  - Avoid formation of gas/mist/vapours.
  - Avoid breathing gas/mist/vapours.
  - The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
- **Breathing equipment:**
  - Under normal conditions, the use of these products should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.
  - Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
- **Protection of hands:**



Protective gloves

- The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
- Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
- Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
- **Material of gloves**
  - The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material** The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:**
  - Wear face shield/eye protection.

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Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

· *Body protection:* Protective work clothing

## 9: Physical and chemical properties

### · Information on basic physical and chemical properties

#### · General Information

##### · Appearance:

· <i>Form:</i>	Liquid
· <i>Color:</i>	Blue
· <i>Odor:</i>	uncharacteristic
· <i>Odour threshold:</i>	Not determined

· <i>pH-value:</i>	>12
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#### · Change in condition

· <i>Melting point/Melting range:</i>	Not applicable
· <i>Boiling point/Boiling range:</i>	Not determined.
· <i>Solidification point:</i>	Not determined

· <i>Flash point:</i>	Not applicable.
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· <i>Flammability (solid, gaseous):</i>	Not applicable
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· <i>Ignition temperature:</i>	Not determined
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· <i>Decomposition temperature:</i>	Not determined
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· <i>Auto igniting:</i>	Product is not selfigniting.
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· <i>Danger of explosion:</i>	Product does not present an explosion hazard.
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· <i>Vapor pressure:</i>	Not determined
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#### · Density:

· <i>Relative density at 20 °C (68 °F)</i>	1.022 g/cm <sup>3</sup> (8.529 lbs/gal)
· <i>Vapour density</i>	Not determined
· <i>Evaporation rate</i>	Not determined

#### · Solubility in / Miscibility with

· <i>Water:</i>	Fully miscible.
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· <i>Partition coefficient (n-octanol/water):</i>	Not determined
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#### · Viscosity:

· <i>Dynamic:</i>	Not determined
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· <b>Other information</b>	No further relevant information available.
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## 10: Stability and reactivity

- **Reactivity** May be corrosive to metals.

- **Chemical stability** Stable under recommended storage conditions.

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

- **Possibility of hazardous reactions** No dangerous reactions if used according to specifications.

- **Conditions to avoid** No further relevant information available.

#### · Incompatible materials:

Strong oxidizing agents, strong acids  
Metals.

#### · Hazardous decomposition products:

Dangerous decomposition products may be formed.  
Carbon oxides (COx)  
Sodium oxides.

- **Additional information:** Stable at the recommended storage temperature and if protected from light. Avoid exposure to heat.

## 11: Toxicological information

### · Information on toxicological effects

#### · Acute toxicity:

· *LD/LC50 values that are relevant for classification:*

#### ATE (Acute Toxicity Estimates)

Oral	LD50	> 5000 mg/kg (rat)
Dermal	LD50	> 5000 mg/kg (rat)

#### 1310-73-2 sodium hydroxide

Oral	LD50	2000 mg/kg (rat)
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**7758-99-8 copper(II) sulfate pentahydrate**

Oral	LD50	960 mg/kg (rat)
	LDL0	1088 mg/kg (human)
Dermal	LD50	> 2000 mg/kg (rat)

- *Primary irritant effect:*
- *on the skin:*  
Causes skin irritation.
- *on the eye:*  
Causes serious eye irritation.
- *Inhalation:*  
May be harmful by inhalation.  
May cause irritating effect.
- *Ingestion:* May be harmful if swallowed.
- *Sensitization:* Data not available
- **Additional toxicological information:** A corrosive effect cannot be ruled out because of the pH value.
- *Carcinogenic categories*
- *IARC (International Agency for Research on Cancer)* None of the ingredient is listed.
- *NTP (National Toxicology Program)* None of the ingredient is listed.

**12: Ecological information**

- **Toxicity**
- **Aquatic toxicity:**  
Harmful to aquatic life with long lasting effects.  
Information on components:


<b>1310-73-2 sodium hydroxide</b>		
EC50/48h	76 mg/l	(Daphnia)
LC50/96h	45.4 mg/l	(Onchorhynchus mykiss)
<b>7758-99-8 copper(II) sulfate pentahydrate</b>		
EC50/48h	0.02 mg/l	(Daphnia)
LC50/96h	0.11 mg/l	(Onchorhynchus mykiss)

- **Persistence and degradability** Data not available
- **Behavior in environmental systems:**
- **Bioaccumulative potential** Data not available
- **Mobility in soil** Data not available
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.  
Rinse off of bigger amounts into drains or the aquatic environment may lead to increased pH-values. A high pH-value harms aquatic organisms.  
Disposal procedures have to be respected, see Section 13.
- **Other adverse effects** No further relevant information available.

**13: Disposal considerations**

- **Waste treatment methods**
- **Recommendation:** Disposal must be made according to official regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Primary packaging:** Plastic vial (composed of polyethylene high density)

**14: Transport information**

· <b>UN-Number</b> · <b>DOT, ADR, IMDG, IATA</b>	UN1824
· <b>UN proper shipping name</b> · <b>DOT</b> · <b>ADR</b> · <b>IMDG, IATA</b>	Sodium hydroxide solution 1824 Sodium hydroxide solution SODIUM HYDROXIDE SOLUTION
· <b>Transport hazard class(es)</b> · <b>DOT</b>	
	
· <b>Class</b>	8 Corrosive substances

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· Label	8
· ADR, IMDG, IATA	
	
· Class	8 Corrosive substances
· Label	8
· Packing group	
· DOT, ADR, IMDG, IATA	III
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	
· Danger code (Kemler):	Warning: Corrosive substances 80
· EMS Number:	F-A,S-B
· Segregation groups	Alkalis
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	
	Not applicable.
· UN "Model Regulation":	UN1824, Sodium hydroxide solution, 8, III

## 15: Regulatory information

- SARA
- Section 302/304 (40CFR355.30 / 40CFR355.40): None of the ingredients is listed.
- Section 313 (Specific toxic chemical listings): Not regulated.
- TSCA (Toxic Substances Control Act): This product is regulated by the Food and Drug Administration; it is exempt from requirements of TSCA.
- Proposition 65
- Chemicals known to cause cancer: None of the ingredients is listed.
- Chemicals known to cause reproductive toxicity for females: None of the ingredients is listed.
- Chemicals known to cause reproductive toxicity for males: None of the ingredients is listed.
- Chemicals known to cause developmental toxicity: None of the ingredient is listed.
- Carcinogenic categories
- EPA (Environmental Protection Agency) None of the ingredient is listed.
- TLV (Threshold Limit Value established by ACGIH) None of the ingredient is listed.
- NIOSH-Ca (National Institute for Occupational Safety and Health) None of the ingredient is listed.
- OSHA-Ca (Occupational Safety & Health Administration) None of the ingredient is listed.
- U. S. State Regulations:

· PA-RTK	
1310-73-2	sodium hydroxide
· NJ-RTK	
1310-73-2	sodium hydroxide
· MA-RTK	
1310-73-2	sodium hydroxide
· RI-RTK	
1310-73-2	sodium hydroxide

- US Federal Regulation This mixture is a component of an FDA-regulated IN VITRO diagnostic medical device.
- Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

## 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- Relevant phrases
- 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.
- Department issuing MSDS: Product safety department
- Contact: Product safety department
- Abbreviations and acronyms:
- SVHC : Substances of Very High Concern
- ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
- IMDG: International Maritime Code for Dangerous Goods
- DOT: US Department of Transportation

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IATA: International Air Transport Association  
GHS: Globally Harmonised System of Classification and Labelling of Chemicals  
ACGIH: American Conference of Governmental Industrial Hygienists  
EINECS: European Inventory of Existing Commercial Chemical Substances  
ELINCS: European List of Notified Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
NOEC : No Observed Effect Concentration  
EC50: Effective concentration, 50 percent  
IC50 : Inhibitory concentration, 50 percent.  
Met. Corr.1: Corrosive to metals, Hazard Category 1  
Acute Tox. 4: Acute toxicity, Hazard Category 4  
Skin Corr. 1A: Skin corrosion/irritation, Hazard Category 1A  
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2  
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2  
Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1  
Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1  
Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

· \* *Data compared to the previous version altered.*

USA