



1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING	
1.1 Product Identifiers	
Product Name	Total Protein (UP)
Cat. No.	UP1570
1.2 Relevant identified uses of the substance or mixture and uses advised against.	For In-vitro Diagnostic Use Do not pipette by mouth. Handle laboratory reagents in accordance with Good Laboratory Practice.
1.3 Details of the supplier of the safety data sheet	
Company	Randox Laboratories Ltd., 55 Diamond Road, Crumlin, Co. Antrim, United Kingdom, BT29 4QY
Telephone	+44 (0) 28 9442 2413
Fax	+44 (0) 28 9445 2912
E-mail Address	sds@randox.com
Website	www.randox.com
1.4 Emergency Telephone Number	
Emergency Phone No.	+44 (0) 28 9442 2413 (GMT, English spoken, Mon - Fri. 08.40-17.20)

2. HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
2.1.1 Regulation (EC) No. 1272/2008 (CLP)	R1. Colour Reagent Eye Irrit. 2: H319; STOT SE 2: H371; CAL. Standard This product contains no hazardous chemicals in reportable quantities according to Regulation (EC) No. 1272/2008 (CLP).
2.1.2 Directive 67/548/EEC & Directive 1999/45/EC	R1. Colour Reagent Xn; R20/21/22-68/20/21/22 CAL. Standard This product contains no hazardous chemicals in reportable quantities according to EU Directives 67/548/EEC or 1999/45/EC.
2.2 Label Elements	
Labelling according to Regulation (EC) No. 1272/2008 (CLP)	
Product Name	Total Protein (UP)
Hazard Pictogram (s)	R1. Colour Reagent  CAL. Standard None Assigned
Signal Word (s)	R1. Colour Reagent Warning

	CAL. Standard None Assigned
Hazard Statement (s)	R1. Colour Reagent Eye Irrit. 2: H319 - Causes serious eye irritation. STOT SE 2: H371 - May cause damage to organs CAL. Standard Not Applicable
Precautionary Statement (s)	R1. Colour Reagent P260 - Do not breathe dust/fume/gas/mist/vapours/spray. P264 - Wash thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P280 - Wear protective gloves/protective clothing/eye protection/face 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. P337+P313 - If eye irritation persists: Get medical advice/attention P501 - Dispose of contents/container according to local / national guidelines. CAL. Standard Not Applicable
2.3 Other Hazards	<p>The Standard contains <0.1% sodium azide. Avoid ingestion or contact with skin or mucous membranes. Sodium azide reacts with lead or copper plumbing to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.</p> <p> Biohazard</p> <p>The Standard contains human serum albumin. This serum has been tested for the HIV (Human Immunodeficiency Virus) Antibody, HCV antibody and Hepatitis B surface antigen using FDA approved methods and found to be negative. However as no method can offer complete assurance as to the absence of infectious agents this material and all patient samples should be handled as though capable of transmitting infectious disease and disposed of accordingly.</p>

3. COMPOSITION/INFORMATION ON INGREDIENTS					
3.1 Substances – Not applicable					
3.2 Mixtures					
EC Classification No. 1272/2008					
Component Name	Hazardous Chemical	Concentration (w/v)	CAS No.	REACH Reg. No.	Hazard Statement(s)
R1. Colour Reagent	Methanol	1 – 10%	67-56-1	Not determined	Flam. Liq. 2: H225; AcuteTox. 3: H331; Acute Tox. 3: H311; Acute Tox. 3: H301; STOT SE 1: H370;
	Succinic Acid	1 – 10%	110-15-6	Not determined	Eye Dam. 1: H318;
EC Classification No. 67/548/EEC					
Component Name	Hazardous Chemical	Concentration (w/v)	CAS No.	REACH Reg. No.	EC Classification and Risk Phrase(s)
R1. Colour Reagent	Methanol	1 – 10%	67-56-1	Not determined	F; R11 T; R23/24/25- 39/23/24/25
	Succinic Acid	1 – 10%	110-15-6	Not determined	Xi; R41

4. FIRST AID MEASURES	
4.1 Description of first aid measures	
Inhalation	If inhaled, move victim to fresh air, rest and maintain a half-upright position. Use artificial respiration if necessary. Immediately seek medical attention.
Skin Contact	If skin contact occurs, remove contaminated clothes, rinse skin with plenty of cold water or shower. Seek medical attention.
Eye Contact	If eye contact occurs, first rinse with plenty of cold water for several minutes, then immediately seek medical attention.
Ingestion	If ingested, rinse mouth. Do not induce vomiting. Give plenty of water to drink. Immediately seek medical attention.
4.2 Most important symptoms and effects, both acute and delayed	None determined
4.3 Indication of any immediate medical attention and special treatment needed	Call an internal person trained in First Aid if available, or contact a physician.

5. FIREFIGHTING MEASURES	
5.1 Extinguishing media	As appropriate for the surrounding fire
5.2 Special hazards arising from the substance or mixture	May emit toxic fumes under fire conditions.
5.3 Advice for firefighters	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

6. ACCIDENTAL RELEASE MEASURES	
6.1 Personal precautions, protective equipment and emergency procedures	Ensure adequate ventilation. Wear appropriate Personal Protective Equipment e.g. laboratory coat, gloves, safety glasses and mask.
6.2 Environmental Precautions	Not determined
6.3 Methods and materials for containment and cleaning up	Use appropriate spill absorbent kit as instructed by the manufacturer. Alternatively mop up with an absorbent material and hold for waste disposal.
6.4 Reference to other sections	Refer to section 8 & 13

7. HANDLING AND STORAGE	
7.1 Precautions for safe handling	Wear personal protective equipment (refer to section 8.2.2). Wash thoroughly after handling. Do not use if skin is cut or scratched. Avoid contact with eyes, skin and clothing. Do not eat, drink or smoke when using this product.
7.2 Conditions for safe storage, including any incompatibilities	Store at temperatures and conditions as indicated on the product label.
7.3 Specific end use (s)	For In-vitro Diagnostic Use

8. EXPOSURE CONTROLS/PERSONAL PROTECTION	
8.1 Control Parameters	Not determined
8.2 Exposure Controls	
8.2.1 Appropriate engineering controls	Ensure adequate ventilation.
8.2.2 Personal protective equipment	
Eye/Face Protection	Approved safety glasses
Hand Protection	Standard laboratory rubber or latex gloves
Skin Protection	A laboratory coat is recommended
Respiratory Protection	None
8.2.3 Environmental Exposure Controls	Not determined

9. PHYSICAL AND CHEMICAL PROPERTIES	
9.1 Information on basic physical and chemical properties	
Appearance	Liquid (R1 and CAL)
Colour	R1 Colour Reagent – Red CAL - Colourless
Odour	Not determined
Odour threshold (ppm)	Not determined
pH Value	R1 Colour Reagent - pH2.5 CAL – Not determined
Melting point / Freezing point	Not determined
Initial boiling point and boiling range	Not determined
Flash point (°C)	Not determined
Evaporation rate	Not determined
Flammability (solid, gas)	Not determined
Upper/lower flammability or explosive limits	Not determined
Vapour pressure	Not determined
Vapour Density	Not determined
Relative Density	Not determined
Solubility (ies)	Not determined
Partition coefficient: (n-octanol/water)	Not determined
Auto ignition temperature (°C)	Not determined
Decomposition temperature (°C)	Not determined
Viscosity (mPa.s)	Not determined
Explosive properties	Not determined
Oxidising properties	Not determined
9.2 Other information	Not determined

10. STABILITY AND REACTIVITY	
10.1 Reactivity	Not determined
10.2 Chemical Stability	Stable under recommended storage conditions
10.3 Possibility of hazardous reactions	Not determined
10.4 Conditions to avoid	Not determined
10.5 Incompatible materials	Not determined
10.6 Hazardous decomposition products	Not determined

11. TOXICOLOGICAL INFORMATION	
11.1 Information on toxicological effects	
<u>Acute toxicity</u>	Not determined
Ingestion	Not determined
Inhalation	Not determined
Skin Contact	Not determined
Eye Contact	Not determined
Skin corrosion/irritation	Not determined
Serious eye damage/eye irritation	Not determined
Respiratory or skin sensitization	Not determined
Germ cell mutagenicity	Not determined
Carcinogenicity	Not determined
Reproductive toxicity	Not determined
STOT – Single exposure	Not determined
STOT- Repeated exposure	Not determined
Aspiration hazard	Not determined
11.2 Other information	Not determined

12. ECOLOGICAL INFORMATION	
12.1 Toxicity	Not determined
12.2 Persistence and degradability	Not determined
12.3 Bioaccumulative potential	Not determined
12.4 Mobility in soil	Not determined
12.5 Results of PBT and vPvB assessment	Not determined
12.6 Other adverse effects	Not determined

13. DISPOSAL CONSIDERATIONS	
13.1 Waste Treatment Methods	Each disposal facility must determine proper disposal methods of the substance or mixture and any contaminated packaging to comply with Local and National Environment Regulations. Refer to section 6.
13.2 Additional Information	Not determined

14. TRANSPORT INFORMATION	
14.1 UN Number	Not applicable
14.2 UN Proper Shipping Name	Not determined
14.3 Transport hazard class (es)	Not applicable
14.4 Packing Group	Not applicable
14.5 Environmental Hazards	Not determined
14.6 Special Precautions for User	Refer to section 7
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable

15. REGULATORY INFORMATION	
This safety data sheet complies with the requirements of EU Regulations 1907/2006 (REACH), 1272/2008 (CLP) & 453/2010.	
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	Not determined
15.2 Chemical Safety Assessments	CSA has not been carried out

16. OTHER INFORMATION
<p>Hazard Class, Hazard Statements and Risk Phrases Description from Section 3</p> <p>R11 - Highly flammable. R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed. R39/23/24/25 - Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed. R41 - Risk of serious damage to eyes.</p> <p>Flam. Liq. 2: H225 - Highly flammable liquid and vapour. Acute Tox. 3: H301 - Toxic if swallowed. Acute Tox. 3: H311 - Toxic in contact with skin. Acute Tox. 3: H331 - Toxic if inhaled. STOT SE 1: H370 - Causes damage to organs. STOT SE 2: H371 - May cause damage to organs.</p> <p>The information provided herein is believed to be correct as of the date hereof but does not purport to be all-inclusive and shall be used only as a guide. The information present in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. The recipient of our products is responsible for observing any National Laws and guidelines applicable.</p>