

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING	
<b>1.1 Product Identifiers</b>	
Product Name	IMMUNOASSAY CONTROL PREMIUM TRI LEVEL
Cat. No.	IA2633
<b>1.2 Relevant identified uses of the substance or mixture and uses advised against.</b>	For <i>in vitro</i> diagnostic use. Do not pipette by mouth. Handle laboratory reagents in accordance with Good Laboratory Practice.
<b>1.3 Details of the supplier of the safety data sheet</b>	
Company	Randox Laboratories Ltd., 55 Diamond Road, Cruclin, Co. Antrim, United Kingdom, BT29 4QY
Telephone	+44 (0) 28 9442 2413
Fax	+44 (0) 28 9445 2912
E-mail Address	<a href="mailto:sds@randox.com">sds@randox.com</a>
Website	<a href="http://www.randox.com">www.randox.com</a>
<b>1.4 Emergency Telephone Number</b>	
Emergency Phone No.	+44 (0) 28 9442 2413 (GMT, English spoken, Mon - Fri. 08.40-17.20)

2. HAZARDS IDENTIFICATION	
<b>2.1 Classification of the substance or mixture</b>	
2.1.1 Regulation (EC) No. 1272/2008 (CLP)	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	This product contains no hazardous chemicals in reportable quantities according to EU Directives 67/548/EEC or 1999/45/EC
<b>2.2 Label Elements</b>	
Labelling according to Regulation (EC) No. 1272/2008 (CLP)	
Product Name	IMMUNOASSAY CONTROL PREMIUM TRI LEVEL
Hazard Pictogram (s)	None assigned
Signal Word (s)	None assigned
Hazard Statement (s)	None assigned
Precautionary Statement (s)	None assigned
<b>2.3 Other Hazards</b>	 <p>Biohazard - The serum in this kit is of human origin. This serum has been tested for the HIV (Human Immunodeficiency Virus) Antibody, HBs Ag and HCV and found to be non-reactive. 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>

<b>3. COMPOSITION/INFORMATION ON INGREDIENTS</b>				
<b>3.1 Substances</b> – Not applicable				
<b>3.2 Mixtures</b>				
EC Classification No. 1272/2008				
Component Name	Chemical Identity of the Substance	Concentration (% w/v)	CAS No.	Hazard Statement(s)
Immunoassay Control Premium Tri Level	None	Not Applicable	Not Applicable	Not Applicable
EC Classification No. 67/548/EEC				
Component Name	Chemical Identity of the Substance	Concentration (% w/v)	CAS No.	EC Classification and Risk phrases
Immunoassay Control Premium Tri Level	None	Not Applicable	Not Applicable	Not Applicable

<b>4. FIRST AID MEASURES</b>	
<b>4.1 Description of first aid measures</b>	
Inhalation	If inhaled, remove to fresh air. If breathing becomes difficult, call a physician.
Skin Contact	In case of skin contact, wash immediately with soap and copious quantities of water.
Eye Contact	Flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating eyelids with fingers. Call a physician.
Ingestion	If swallowed wash out mouth with water, provided person is conscious. Call a physician.
<b>4.2 Most important symptoms and effects, both acute and delayed</b>	May cause irritation to skin and eyes, may be irritating to mucous membranes and upper respiratory tract. Avoid contact with skin, inhalation and ingestion.
<b>4.3 Indication of any immediate medical attention and special treatment needed</b>	Call an internal person trained in First Aid if available, or contact a physician.

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

6. ACCIDENTAL RELEASE MEASURES	
<b>6.1 Personal precautions, protective equipment and emergency procedures</b>	<b>Precaution</b> Treat material as you would human body fluids. Wear appropriate personal protective equipment (see section 8.2.2)
<b>6.2 Environmental Precautions</b>	None determined
<b>6.3 Methods and materials for containment and cleaning up</b>	Treat material as you would human body fluids. Disposal should, therefore include autoclaving at 121°C for 20 minutes prior to appropriate disposal with regard to local regulations.  Alternatively, decontamination using a 0.1% sodium hypochlorite is acceptable. Perform this type of decontamination in a fume hood.
<b>6.4 Reference to other sections</b>	Refer to Section 8 & 13

7. HANDLING AND STORAGE	
<b>7.1 Precautions for safe handling</b>	Wear personal protective equipment (see 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.
<b>7.2 Conditions for safe storage, including any incompatibilities</b>	Store at temperatures and conditions as indicated on the product label.
<b>7.3 Specific end use (s)</b>	<i>In vitro</i> diagnostic use

8. EXPOSURE CONTROLS/PERSONAL PROTECTION	
<b>8.1 Control Parameters</b>	Not determined
<b>8.2 Exposure Controls</b>	
<b>8.2.1 Appropriate engineering controls</b>	Ensure adequate ventilation.
<b>8.2.2 Personal protective equipment</b>	
Eye/Face Protection	Protective glasses
Hand Protection	Standard laboratory rubber or latex gloves
Skin Protection	Laboratory coat
Respiratory Protection	Not applicable
<b>8.2.3 Environmental Exposure Controls</b>	Not determined

<b>9. PHYSICAL AND CHEMICAL PROPERTIES</b>	
<b>9.1 Information on basic physical and chemical properties</b>	
Appearance	Lyophilised
Colour	Pale yellow liquid when reconstituted
Odour	Not determined
Odour threshold (ppm)	Not determined
pH	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
<b>9.2 Other information</b>	No data available

<b>10. STABILITY AND REACTIVITY</b>	
<b>10.1 Reactivity</b>	Not determined
<b>10.2 Chemical Stability</b>	Stable
<b>10.3 Possibility of hazardous reactions</b>	Not determined
<b>10.4 Conditions to avoid</b>	Not determined
<b>10.5 Incompatible materials</b>	Strong oxidizing agents and acids
<b>10.6 Hazardous decomposition products</b>	Not determined

<b>11. TOXICOLOGICAL INFORMATION</b>	
<b>11.1 Information on toxicological effects</b>	
Acute toxicity	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
<b>11.2 Other information</b>	The serum in this kit is of human origin. See section 2.3.

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

<b>13. DISPOSAL CONSIDERATIONS</b>	
<b>13.1 Waste Treatment Methods</b>	<p>Treat material as you would human body fluids. Disposal should, therefore include autoclaving at 121°C for 20 minutes prior to appropriate disposal with regard to local regulations.</p> <p>Alternatively, decontamination using a 0.1% sodium hypochlorite is acceptable. Perform this type of decontamination in a fume hood.</p>
<b>13.2 Additional Information</b>	Not determined

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

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

<b>16. OTHER INFORMATION</b>	
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.	