



<b>1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING</b>	
<b>1.1 Product Identifiers</b>	
Product Name	Assayed Human Multi-Sera – Level 2 (HUM ASY CONTROL 2)
Cat. No.	HN1530
<b>1.2 Relevant identified uses of the substance or mixture and uses advised against.</b>	For <i>in vitro</i> diagnostic use only. 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, Crumlin, 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	www.randox.com
<b>1.4 Emergency Telephone Number</b>	
Emergency Phone No.	+44 (0) 28 9442 2413 (GMT, English spoken, Mon - Fri. 08.40-17.20)

<b>2. HAZARDS IDENTIFICATION</b>	
<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.
2.1.3 Other	 NFPA 704 —
<b>2.2 Label Elements</b>	
<b>Labelling according to Regulation (EC) No. 1272/2008 (CLP)</b>	
Product Name	Assayed Human Multi-Sera – Level 2 (HUM ASY CONTROL 2)
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>	 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.

<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	Hazardous Chemical	Concentration (w/v)	CAS No.	REACH Reg. No.	Hazard Statement(s)
Assayed Human Multi-Sera – Level 2	None	Not Applicable	Not Applicable	Not Applicable	Not Applicable
EC Classification No. 67/548/EEC					
Component Name	Hazardous Chemical	Concentration (w/v)	CAS No.	REACH Reg. No.	EC Classification and Risk Phrase(s)
Assayed Human Multi-Sera – Level 2	None	Not Applicable	Not Applicable	Not Applicable	Not Applicable

<b>4. FIRST AID MEASURES</b>	
<b>4.1 Description of first aid measures</b>	
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.
<b>4.2 Most important symptoms and effects, both acute and delayed</b>	Not determined
<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 the 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 (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.
<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	Approved safety glasses
Hand Protection	Standard laboratory rubber or latex gloves
Skin Protection	A laboratory coat is recommended
Respiratory Protection	None
<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	Straw coloured liquid when reconstituted.
Odour	None
Odour threshold (ppm)	Not determined
pH Value	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>	None

<b>10. STABILITY AND REACTIVITY</b>	
<b>10.1 Reactivity</b>	Not determined
<b>10.2 Chemical Stability</b>	Stable under recommended storage conditions
<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>	Not determined
<b>10.6 Hazardous decomposition products</b>	Not determined

<b>11. TOXICOLOGICAL INFORMATION</b>	
<b>11.1 Information on toxicological effects</b>	
<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
<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

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	
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.	