

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING	
1.1 Product Identifiers	
Product Name	IMMUNOASSAY SPECIALITY I - LEVEL 3 (IA SPECIALITY I LEV 3)
Cat. No.	IAS3115
1.2 Relevant identified uses of the substance or mixture and uses advised against.	<i>For in-vitro diagnostic use.</i> 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)

SECTION 2. HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
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 Additional Information	Not applicable
2.2 Label Elements	
Labelling according to Regulation (EC) No. 1272/2008 [CLP]	
Product Name	IMMUNOASSAY SPECIALITY I - LEVEL 3 (IA SPECIALITY I LEV 3)
Hazard Pictogram (s)	None assigned
Signal Word (s)	None assigned
Hazard Statement (s)	None assigned
Precautionary Statement (s)	None assigned
Supplemental Hazard information (EU)	None assigned
2.3 Other Hazards	 Biohazard The product contains material of human origin. This material 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.

SECTION 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)
Immunoassay Speciality I - Level 3	None	Not Applicable	Not Applicable	Not Applicable	Not Applicable

SECTION 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.
Self-protection of the first aider	Wear appropriate personal protective equipment (see section 8.2.2)
4.2 Most important symptoms and effects, both acute and delayed	May cause irritation to skin and eyes, may be irritating to mucous membranes and upper respiratory tract. Avoid contact with skin, inhalation and ingestion.
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.

SECTION 5. FIREFIGHTING MEASURES	
5.1 Extinguishing media	As appropriate for 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.

SECTION 6. ACCIDENTAL RELEASE MEASURES	
6.1 Personal precautions, protective equipment and emergency procedures	Precaution -Treat material as you would human body fluids. Wear appropriate personal protective equipment (see section 8.2.2)
6.2 Environmental Precautions	None determined
6.3 Methods and materials for containment and cleaning up	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.
6.4 Reference to other sections	Refer to Section 8 & 13

SECTION 7. HANDLING AND STORAGE	
7.1 Precautions for safe handling	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.
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 <i>in-vitro</i> diagnostic use.

SECTION 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	Laboratory coat
Respiratory Protection	None
8.2.3 Environmental Exposure Controls	Not determined

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES	
9.1 Information on basic physical and chemical properties	
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)	Soluble in water

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

SECTION 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

SECTION 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
Summary of evaluation of the CMR properties	Not determined
STOT – Single exposure	Not determined
STOT- Repeated exposure	Not determined
Aspiration hazard	Not determined
11.2 Other information	The product contains material of human origin. See section 2.3.

SECTION 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
12.7 Additional information	Not determined

SECTION 13. DISPOSAL CONSIDERATIONS	
13.1 Waste Treatment Methods	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.
13.2 Additional Information	Not determined

SECTION 14. TRANSPORT INFORMATION	
14.1 UN Number	Not regulated as a dangerous good
14.2 UN Proper Shipping Name	Not regulated as a dangerous good
14.3 Transport hazard class (es)	Not regulated as a dangerous good
14.4 Packing Group	Not regulated as a dangerous good
14.5 Environmental Hazards	Not regulated as a dangerous good
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

SECTION 15. REGULATORY INFORMATION	
This safety data sheet complies with the requirements of Regulation (EU) 2015/830	
15.1 Safety, health and environmental Regulations/legislation specific for the substance or mixture	Not determined
15.2 Chemical Safety Assessments	A CSA has not been carried out

SECTION 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.