SAFETY DATA SHEET

According to Regulations (EU) 2020/878

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING	
1.1 Product Identifiers	
Product Name	**HUMAN PRECISION CONTROL (HUM PREC CONTROL 3)**
Cat. No.	UE1558
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)

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	HUMAN PRECISION CONTROL (HUM PREC CONTROL 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. The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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)	Specific Concentration limit, M-factor, and acute toxicity estimate
HUMAN PRECISION CONTROL	None	Not Applicable	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	
6.1.1 For non-emergency personnel	Precaution -Treat material as you would human body fluids. Wear appropriate personal protective equipment (see section 8.2.2)
6.1.2 For emergency responders	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)	*In vitro 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 Individual protection measures, such as personal protective equipment	
(a) Eye/Face Protection	Approved safety glasses
(b) Skin protection	
Hand Protection	Standard laboratory rubber or latex gloves
Other	Laboratory coat
(c) Respiratory Protection	Not applicable
(d) Thermal hazards	Not determined
8.2.3 Environmental Exposure Controls	Not determined

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES	
9.1 Information on basic physical and chemical properties	
Physical State	Solid
Colour	Pale yellow
Odour	Not determined

pH	Not determined
Melting point / Freezing point	Not determined
Boiling point or initial boiling point and boiling range	Not determined
Flash point (°C)	Not determined
Flammability (solid, liquid, gas)	Not determined
Lower and upper explosion limit	Not determined
Vapour pressure	Not determined
Density and/or relative density	Not determined
Relative vapour 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
Kinematic viscosity (mPa.s)	Not determined
Particle Characteristics	Not determined
9.2 Other information	
9.2.1 Information with regards to physical hazard classes	
Explosive properties	Not determined
Oxidising properties	Not determined
9.2.2 Other safety characteristics	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	Strong oxidizing agents and acids
10.6 Hazardous decomposition products	Not determined

SECTION 11. TOXICOLOGICAL INFORMATION	
11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008	
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
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 Information on other Hazards	
11.2.1 Endocrine disrupting properties	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
11.2.2 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	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
12.6 Endocrine disrupting properties	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
12.7 Other adverse effects	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.

SECTION 14. TRANSPORT INFORMATION	
14.1 UN Number or ID Number	Not classified as hazardous for transport
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 Maritime transport in bulk according to IMO instruments	Not applicable

SECTION 15. REGULATORY INFORMATION

This safety data sheet complies with the requirements of Regulation (EU) 2020/878

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

Text of Hazard Statements in Section 3

None

Relevant changes since previous revision

Changes to meet new Regulations 2020/878

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.