# SAFETY DATA SHEET

| 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING | |
|---|---|
| **1.1 Product Identifiers** | |
| Product Name | HAEMOGLOBIN A1c CONTROL SET (HbA1c CONTROL) |
| Cat. No. | HA5072 |
| **1.2 Relevant identified uses of the substance or mixture and uses advised against.** | For *in vitro* diagnostic use.<br>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<br>(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) | 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 |
| **2.2 Label Elements** | |
| Labelling according to Regulation (EC) No. 1272/2008 (CLP) | |
| Product Name | HAEMOGLOBIN A1c CONTROL SET (HbA1c CONTROL) |
| Hazard Pictogram (s) | None assigned |
| Signal Word (s) | None assigned |
| Hazard Statement (s) | None assigned |
| Precautionary Statement (s) | None assigned |
| **2.3 Other Hazards** | <br>Biohazard - The material in this kit is of human origin. This material has been tested for the HIV (Human Immunodeficiency Virus) Antibody, HBsAg 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. |

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

**3.1 Substances** – Not applicable

**3.2 Mixtures**

EC Classification No. 1272/2008

| Component Name | Chemical Identity of the Substance | Concentration (% w/v) | CAS No. | Hazard Statement(s) |
|---|---|---|---|---|
| HAEMOGLOBIN A1c CONTROL SET | 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 |
|---|---|---|---|---|
| HAEMOGLOBIN A1c CONTROL SET | None | Not Applicable | Not Applicable | Not Applicable |

## 4. FIRST AID MEASURES

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| **4.1 Description of first aid measures** | |
| 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. |
| **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. |

## 5. FIREFIGHTING MEASURES

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| **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. |

| 6. ACCIDENTAL RELEASE MEASURES | |
|---|---|
| **6.1 Personal precautions, protective equipment and emergency procedures** | **Precaution**<br>Treat material as you would human body fluids.<br>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.<br><br>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 |

| 7. HANDLING AND STORAGE | |
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| **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 |

| 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 | Protective glasses |
| Hand Protection | Standard laboratory rubber or latex gloves |
| Skin Protection | Laboratory coat |
| Respiratory Protection | Not applicable |
| **8.2.3 Environmental Exposure Controls** | Not determined |

| 9. PHYSICAL AND CHEMICAL PROPERTIES | |
|---|---|
| **9.1 Information on basic physical and chemical properties** | |
| Appearance | Lyophilised |
| Colour | Red when reconstituted |
| Odour | None |
| Odour threshold (ppm) | Not determined |
| pH | Not determined |
| Melting point / Freezing point | Not determined |
| Initial boiling point and boiling range | Not determined |
| Flash point ($^{o}$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 ($^{o}$C) | Not determined |
| Viscosity (mPa.s) | Not determined |
| Explosive properties | Not determined |
| Oxidising properties | Not determined |
| **9.2 Other information** | No data available |

| 10. STABILITY AND REACTIVITY | |
|---|---|
| **10.1 Reactivity** | Not determined |
| **10.2 Chemical Stability** | Stable |
| **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 |

| 11. TOXICOLOGICAL INFORMATION | |
|---|---|
| **11.1 Information on toxicological effects** | |
| Acute toxicity<br>Ingestion<br>Inhalation<br>Skin Contact<br>Eye Contact | Not determined<br>Not determined<br>Not determined<br>Not determined<br>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** | The material in this kit is of human origin. See section 2.3. |

| 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** | 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.<br><br>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 |

| 14. TRANSPORT INFORMATION | |
|---|---|
| **14.1 UN 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 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** | Not applicable |

| 15. REGULATORY INFORMATION<br>This safety data sheet complies with the requirements of EU Regulations 1907/2006 (REACH), 1272/2008 (CLP) & 453/2010. | |
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| **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 |

| 16. OTHER INFORMATION |
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| 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. |