

1. Information of the substance/mixture and of the company/undertaking	
1.1 Commercial product name	HbA1c Kit
Cat. No.:	HA3830
1.2 Company:	RANDOX Laboratories Ltd., 55 Diamond Road, Crumlin, Co. Antrim, United Kingdom, BT29 4QY Tel: +44 (0) 28 9442 2413; Fax: +44 (0) 28 9445 2912 Email: msds@randox.com Website: www.randox.com
1.3 In Emergencies:	Tel: +44 (0) 28 9442 2413

2. Hazards identification	
<u>HbA1c R1 Antibody Reagent</u> Chemical Name: Proclin 150	Contains no hazardous substances in reportable quantities 0.1%
Classification:	No hazardous chemicals as classified by CHIP 3
<u>HbA1c R2 Agglutinator Reagent</u> Chemical Name: Proclin 150	Contains no hazardous substances in reportable quantities 0.1%
Classification:	No hazardous chemicals as classified by CHIP 3
<u>Total Haemoglobin Reagent</u> Chemical Name: Sodium Hydroxide Octylphenoxypoly Ethoxyethanol Triton X-100	Contains no hazardous substances in reportable quantities 0.4% (Exposure limit: 2 mg/m ³ PEL-TWA, 2 mg/m ³ TLV-Ceiling) 2.5% (Exposure limit: None established) 2.5%
Classification:	No hazardous chemicals as classified by CHIP 3
<u>Haemoglobin Denaturant</u> Chemical Name: N/A	Contains no hazardous substances in reportable quantities
Classification:	No hazardous chemicals as classified by CHIP 3

3. Composition / Information on Ingredients	
<u>HbA1c R1 Reagent</u> Warnings: Risk phrases: Safety phrases:	For <i>in vitro</i> diagnostic use only. Do not pipette by mouth. Handle laboratory reagents in accordance with Good Laboratory Practice. Avoid contact with skin, avoid inhalation and ingestion. None None
<u>HbA1c R2 Reagent</u> Warnings: Risk phrases: Safety phrases:	For <i>in vitro</i> diagnostic use only. Do not pipette by mouth. Handle laboratory reagents in accordance with Good Laboratory Practice. Avoid contact with skin, avoid inhalation and ingestion. None None
<u>Total Haemoglobin Reagent</u> Warnings: Risk phrases: Safety phrases:	For <i>in vitro</i> diagnostic use only. Do not pipette by mouth. Handle laboratory reagents in accordance with Good Laboratory Practice. May cause eye/skin irritation. Avoid contact with skin, avoid inhalation and ingestion. None None
<u>Haemoglobin Denaturant</u> Warnings: Risk phrases: Safety phrases:	For <i>in vitro</i> diagnostic use only. Do not pipette by mouth. Handle laboratory reagents in accordance with Good Laboratory Practice. Avoid contact with skin, avoid inhalation and ingestion. None None

4. First aid measures HbA1c R1 rgt, HbA1c R2 rgt & Haemoglobin Denaturant	
Emergency First Aid: Inhalation: Ingestion: Skin Contact: Eye Contact:	Call a physician immediately. Arrange for transport to the nearest ER (emergency room). While awaiting the physical or transport to the ER: If it occurs move patient to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. If the patient is conscious, rinse out mouth with water and have the patient drink a glass of water or milk to dilute the material. Transport to hospital for further medical attention. Remove any contaminated clothing. Wash off with soap and water. Wash contaminated clothing before re-use. In case of eye contact immediately flush eyes with copious amounts of water for at least 15-20 minutes. Rinse thoroughly with plenty of water, also under the eyelids. Transport to hospital for further medical attention.
First aid measures Total Haemoglobin rgt	
Emergency First Aid: Inhalation:	Call a physician immediately. Arrange for transport to the nearest ER (emergency room). While awaiting the physician or transport to the ER: If it occurs move patient to fresh air. If not breathing, give artificial respiration. If breathing is

Ingestion:	difficult, give oxygen. If the patient is conscious, rinse out mouth with water and have the patient drink a glass of water or milk to dilute the material. Get immediate medical attention.
Skin Contact:	Take off contaminated clothing immediately. Wash off immediately with soap and plenty of water. Get medical attention if irritation persists. Wash contaminated clothing before re-use.
Eye Contact:	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get immediate medical attention.

5. Fire-fighting measures	
Flash point:	None
Flammable limits:	N/A
Extinguishing media:	Use whatever is required for the surrounding area.
Special Fire Fighting Procedures:	Wear self contained breathing apparatus
Unusual Fire and Explosion Hazards:	None determined
Thermal decomposition:	Not determined

6. Accidental release measures	
<u>HbA1c R1 rgt, HbA1c R2 rgt & Haemoglobin Denaturant</u> After spillage:	Take up with absorbent material and place in a suitable container. Wipe up area with a damp paper towel and discard. Appropriate Personal Protective Equipment should be worn, e.g. laboratory coat, gloves, safety glasses and mask. Ventilate area and wash spill site after material pick up is complete.
Absorbent material:	No restriction
<u>Total Haemoglobin rgt</u> After spillage:	Dilute spill with water. Neutralise with dilute acetic acid. Take up with absorbent material and place in a suitable container. Wipe up area with a damp paper towel and discard. Appropriate Personal Protective Equipment should be worn, e.g. laboratory coat, gloves, safety glasses and mask. Ventilate area and wash spill site after material pick up is complete.
Absorbent material:	No restriction

7. Handling and storage	
7.1 Handling:	Wash thoroughly after handling. Do not use if skin is cut or scratched. Avoid contact with eyes, skin and clothing.
7.2 Storage	Store at temperatures and conditions as indicated on the product label
Do not store together:	N/A

8. Exposure controls/personal protection	
MEL/OES	Not determined
Respiratory protection:	None required
Ventilation	Use general room ventilation
Eye protection:	Protective glasses
Hand protection:	Standard laboratory rubber or latex gloves.
Skin protection:	A laboratory coat or apron is recommended

9. Physical and chemical properties for HbA1c R1 rgt	
Physical state:	Liquid
Colour:	White suspension in aqueous solution
Odour:	No odour
pH value:	8.1
Boiling point	Not determined
Melting point:	Not applicable
Oxidising properties:	Not determined
Ignition temperature	Not determined
Explosion limits:	Not determined
Density:	Not determined
Solubility in water:	Insoluble

9. Physical and chemical properties for HbA1c R2 rgt	
Physical state:	Liquid
Colour:	Clear, colourless solution
Odour:	Not determined
pH value:	2.0
Boiling point	Not determined
Melting point:	Not applicable
Oxidising properties:	Not determined
Ignition temperature	Not determined
Explosion limits:	Not determined
Density:	Not determined
Solubility in water:	Soluble

9. Physical and chemical properties for Total Haemoglobin rgt	
Physical state:	Liquid
Colour:	Clear, colourless solution
Odour:	Not determined
pH value:	13
Boiling point	Not determined
Melting point:	Not applicable
Oxidising properties:	Not determined
Ignition temperature	Not determined
Explosion limits:	Not determined
Density:	Not determined
Solubility in water:	Soluble

9. Physical and chemical properties for Haemoglobin Denaturant	
Physical state:	Liquid
Colour:	Clear, colourless solution
Odour:	Not determined
pH value:	2.4
Boiling point	Not determined
Melting point:	Not applicable
Oxidising properties:	Not determined
Ignition temperature	Not determined
Explosion limits:	Not determined
Density:	Not determined
Solubility in water:	Soluble

10. Stability and reactivity for HbA1c R1 rgt, HbA1c R2 rgt & Haemoglobin Denaturant	
Stability:	Stability:
Conditions to avoid:	Conditions to avoid:
Substances to avoid:	Substances to avoid:
Hazardous decomposition products:	Hazardous decomposition products:

10. Stability and reactivity for Total Haemoglobin rgt	
Stability:	Stable
Conditions to avoid:	Avoid excessive heat
Substances to avoid:	Avoid strong acids and metals

Hazardous decomposition products:	None determined
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11. Toxicological information for HbA1c R1 rgt, HbA1c R2 rgt & Haemoglobin Denaturant	
LD50 oral	LD50 oral
LD50 intraperitoneal	LD50 intraperitoneal
LD50 skin	LD50 skin
LC50 inhalation	LC50 inhalation
<p>Toxicological information:</p> <p>Chronic effects of overexposure:</p> <p>Carcinogen or suspected carcinogen:</p> <p>Medical conditions aggravated by exposure:</p> <p>Acute toxicity:</p> <p>Inhalation:</p> <p>Ingestion:</p> <p>Skin contact:</p> <p>Eye contact:</p> <p>Acute toxicity values:</p>	<p>Toxicological information:</p> <p>Chronic effects of overexposure:</p> <p>Carcinogen or suspected carcinogen:</p> <p>Medical conditions aggravated by exposure:</p> <p>Acute toxicity:</p> <p>Inhalation:</p> <p>Ingestion:</p> <p>Skin contact:</p> <p>Eye contact:</p> <p>Acute toxicity values:</p>

11. Toxicological information for T.Hb rgt	
LD50 oral	LD50 oral rat: Sodium hydroxide:140 – 340mg/kg Octyl Phenoxy Polyethoxy Ethanol: 5 gm/kg
LD50 intraperitoneal	Not determined
LD50 skin	Not determined
LC50 inhalation	Not determined
<p>Toxicological information:</p> <p>Chronic effects of overexposure:</p> <p>Carcinogen or suspected carcinogen:</p> <p>Medical conditions aggravated by exposure:</p> <p>Acute toxicity:</p> <p>Inhalation:</p> <p>Ingestion:</p> <p>Skin contact:</p> <p>Eye contact:</p> <p>Acute toxicity values:</p>	<p>Not thoroughly investigated</p> <p>Repeated contact with dilute sodium hydroxide solutions may cause dermatitis. None of the components are listed as a carcinogen or suspected carcinogen.</p> <p>Pre-existing skin diseases and conditions.</p> <p>Inhalation of mists may cause mucous membrane and respiratory irritation. Swallowing may cause gastrointestinal irritation. Contact may cause mild irritation with redness, pain and swelling. Contact may cause irritation with possibly burns on prolonged contact.</p> <p>LD50 oral rat: Sodium hydroxide:140 – 340mg/kg Octyl Phenoxy Polyethoxy Ethanol: 5 gm/kg</p>

12. Ecological information	
HbA1c R1 rgt	
Water hazard class:	Data not yet available
	<p>Ecological effects of this mixture have not been determined.</p> <p>This product contains 0.1% Proclin 150 which contains 1.2% 5-chloro-2-methyl-4-isothiazolin-3-one & 0.4% 2-methyl-4-isothiazolin-3-one. The active ingredients have a 48 hr EC50 of 0.16ppm in Daphnia Magna & a LC50 in Rainbow Trout of 0.19ppm.</p> <p>This product also contains approximately <0.1% of suspended latex particles.</p> <p>This product contains 0.6% of a non-ionic surfactant.</p>
HbA1c R2 rgt	
Water hazard class:	Data not yet available
	<p>Ecological effects of this mixture have not been determined.</p> <p>This product contains 0.1% Proclin 150 which contains 1.2% 5-chloro-2-methyl-4-isothiazolin-3-one & 0.4% 2-methyl-4-isothiazolin-3-one. The active ingredients have a 48 hr EC50 of 0.16ppm in Daphnia Magna & a LC50 in Rainbow Trout of 0.19ppm.</p> <p>This product contains 0.2% of a non-ionic surfactant.</p>
Total Haemoglobin rgt	
Water hazard class:	Data not yet available
	<p>Ecological effects of this mixture have not been determined.</p> <p>This product contains 2.5% of a surfactant, Triton X-100 which has a reported TL50 for bluegill sunfish of 12mg/L/96hr static.</p>
Haemoglobin Denaturant	
Water hazard class:	Data not yet available
	Ecological effects of this mixture have not been determined.
13. Disposal considerations	<p>Each disposal facility must determine proper disposal methods of the substance or preparation and any contaminated packaging to comply with Local and National Environmental Regulations</p> <p>Refer to Section 6.</p>

14. Transport Information

HbA1c R1 rgt, HbA1c R2 rgt & Haemoglobin Denaturant
Drop on shipping purposes. Not regulated.

Proper shipping name: Not regulated

Technical name:

UN number: N/A
Hazard class and packaging group: Not regulated

Hazard class and packaging group: Not regulated

Label(s): N/A

Packing Instruction (passenger aircraft): N/A
Packing Instruction (Cargo Aircraft): N/A

Packing Instruction (Cargo Aircraft): N/A

Unit Volume: 23 mL for HbA1c R1 rgt & HbA1c R2 rgt

110 mL for Total Haemoglobin rgt

Primary Container Type: 30 mL Amber plastic, HD polyethylene for HbA1c R1 rgt & HbA1c R2 rgt
125 mL Plastic, HD polyethylene

Sales Unit: 1 bottle / kit

Total Haemoglobin rgt: Proper shipping name: Sodium hydroxide solution	
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Technical name:

UN number: UN1824
Hazard class and packaging group: 8, III

Label(s): Corrosive

Packing Instruction (Cargo Aircraft): LATA 821 (60 L max, 5 L max inner pkg)

Unit Volume: 38 mL

Primary Container Type: 125 mL Plastic, HD polyethylene
Sales Unit: 1 bottle / kit

GGVE/GGVS:	Data not yet available	RID/ADR	Data not yet available
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ICAO/IATA-DGR:	Data not yet available	UN-Nr.:	Data not yet available
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IMDG-CODE:	Data not yet available	MFAG	Data not yet available
		ENC	Data not yet available

		EMS:	Data not yet available
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GGVE/GGVS:	Data not yet available	RID/ADR	Data not yet available
ICAO/IATA-DGR:	Data not yet available	UN-Nr.:	Data not yet available
IMDG-CODE:	Data not yet available	MFAG	Data not yet available
		EMS:	Data not yet available

15. Regulatory information	
HbA1c R1 Reagent	This product contains no hazardous chemicals in reportable quantities according to CHIP 3.
Hazard symbol:	None
Risk phrases:	None
Safety phrases:	None
Precautions:	See Section 3
HbA1c R2 Reagent	This product contains no hazardous chemicals in reportable quantities according to CHIP 3.
Hazard symbol:	None
Risk phrases:	None
Safety phrases:	None
Precautions:	See Section 3
Total Haemoglobin Reagent	This product contains no hazardous chemicals in reportable quantities according to CHIP 3.
Hazard symbol:	None
Risk phrases:	None
Safety phrases:	None
Precautions:	See Section 3
Haemoglobin Denaturant	This product contains no hazardous chemicals in reportable quantities according to CHIP 3.
Hazard symbol:	None
Risk phrases:	None
Safety phrases:	None
Precautions:	See Section 3

16. Other information	
	The information herein is believed to be correct as of the date hereof but is provided without warranty of any kind. The recipient of our products is responsible for observing any National laws and guidelines applicable.