SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

HbA1c (GHb) Calibrator Kit

Revision 4
Revision date 2013-03-22

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name	HbA1c (GHb) Calibrator Kit
Product code	01-04-0018, 01-04-0022

1.2. Relevant identified uses of the substance or mixture and uses advised against

Description	For the calibration of Quantitative Glycated Hemoglobin Assays. For in Vitro Diagnostic Use only.

1.3. Details of the supplier of the safety data sheet

Company	Trinity Biotech
Address	IDA Business Park Bray Co. Wicklow Ireland
Web	www.trinitybiotech.com
Telephone	+353 1 276 9800
Fax	+353 1 276 9883
Email	info@trinitybiotech.com
Local Supplier	
Company	Trinity Biotech USA
Address	2823 Girts Rd Jamestown NY 14701 USA
Telephone	+1 800-325-3424
Fax	+1 716-487-1419

1.4. Emergency telephone number

	Contact your local Emergency Health Provider. Ireland-Technical Support Group 00353 -1- 276- 9800 USA-Technical Support Group 1-800-325-3424

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Main hazards	No Significant Hazard

2.2. Label elements

Risk phrases	No Significant Hazard

2.3. Other hazards

Other hazards	All blood donor units have been tested and found non-reactive for Hepatitis B surface antigen and HIV 1 and 2 and HCV antibodies when tested by FDA accepted methods. However, no known test method can assure that a product derived from blood does not contain Hepatitis or HIV virus. Handle as if potentially infectious.

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SECTION 3: Composition/information on ingredients

3.1. Substances

67/548/EEC / 1999/45/EC

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Human Whole Blood					90 - 100%		

EC 1272/2008

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Human Whole Blood					90 - 100%		

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	No Significant Hazard.
Eye contact	May cause irritation to eyes. Wear eye/face protection. Rinse immediately with plenty of water.
Skin contact	Wash with soap and water.
Ingestion	No Significant Hazard. Wear suitable gloves. Avoid contact with skin. Seek medical attention.

General information

	Use universal precautions for handling as with human blood. Remove contaminated clothing. Wash with soap and water.

SECTION 5: Firefighting measures

5.1. Extinguishing media

	Use extinguishing media appropriate to the surrounding fire conditions.

5.2. Special hazards arising from the substance or mixture

	None.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

	Wear suitable gloves and eye/face protection. Wear suitable protective clothing. Handle spilled material under universal precautions and protections, as with patient blood samples.

6.2. Environmental precautions

	This product readily biodegrades and does not present an environmental hazard in the (1) aquatic (including sediment), (2) terrestrial, (3) atmospheric, or (4) food-chain via accumulation.

6.3. Methods and material for containment and cleaning up

	Wash with soap and water.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

	Keep tightly closed. Keep frozen until used. Glass container is fragile. Read and review the package insert for additional handling instructions. All blood donor units have been tested and found non-reactive for Hepatitis B surface antigen and HIV 1 and 2 and HCV antibodies when tested by FDA accepted methods. However, no known test method can assure that a product derived from blood does not contain Hepatitis or HIV virus. Handle as if potentially infectious.

7.2. Conditions for safe storage, including any incompatibilities

	Store in original container.

7.3. Specific end use(s)

	For in Vitro Diagnostic Use only.

SECTION 8: Exposure controls/personal protection

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8.2. Exposure controls

Eye / face protection	Wear suitable protective clothing and eye/face protection.
Skin protection - Handprotection	Wear suitable gloves.
Skin protection - Other	Wear suitable protective clothing.
Respiratory protection	Not normally required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Powder
Colour	Red
Solubility	Soluble in water

SECTION 10: Stability and reactivity

10.4. Conditions to avoid

	None.

10.5. Incompatible materials

	None.

10.6. Hazardous decomposition products

	None.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	None.
Skin corrosion/irritation	Avoid contact with skin.
Serious eye damage/irritation	Avoid contact with eyes.
Respiratory or skin sensitisation	None.
Repeated or prolonged exposure	None.

SECTION 12: Ecological information

12.2. Persistence and degradability

	The blood component of this product readily biodegrades and does not present any environmental hazard related to persistence in the environment or hazardous degradation intermediates. The glass vial does not present any environmental hazard related to persistence in the environment or hazardous degradation intermediates. The empty glass vial is typically collected for disposal with biohazard waste under universal precautions.

12.3. Bioaccumulative potential

	This product readily biodegrades and does not present an environmental hazard in the (1) aquatic (including sediment), (2) terrestrial, (3) atmospheric, or (4) food-chain via accumulation.

12.4. Mobility in soil

	None.

12.6. Other adverse effects

	None.

SECTION 13: Disposal considerations

Further information

	Disposal should be made in accordance with local and national regulations.

SECTION 14: Transport information

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Further information

	This product is not regulated during transportation, except where regulations apply to blood products. Keep frozen and protect from elevated temperatures. Return to freezer immediately upon receipt. Glass containers are fragile, handle with care.

SECTION 15: Regulatory information

Further information

	For in Vitro Diagnostic Use only.

SECTION 16: Other information

Other information

	The information contained in this MSDS does not purport to be all-inclusive and is provided for general guidance only. The manufacturer is not liable for any damage resulting from mishandling or unprotected contact with the above product.
Revision	This document differs from the previous version in the following areas:. 1 - Description.