

1. Information of the substance/preparation and of the company	
1.1 Commercial product name	HbA1c Control Set
Cat. No.	KG3445
1.2. Company	BGT BioGenTechnologies GmbH Von-Langen-Weg 10 D-48565 Steinfurt Tel.: 02551/4090 Fax.: 02551/1298
1.3. In Emergencies	Tel.: 02551/4090

2. Composition / Hazardous Ingredients	
Reconstitution Fluid	Sodium Azide - 0.09%
Classification:	No hazardous chemicals as classified by CHIP 3
HbA1c Level 1 & Level 2 Control	Contains no hazardous substances in reportable quantities. Note: This product contains material derived from human sources and may be considered a biohazard and / or Regulated Waste. Check your Local Environmental Regulations.
Classification:	No hazardous chemicals as classified by CHIP 3

3. Hazards identification	
Reconstitution Fluid	
Warnings:	For <i>in vitro</i> diagnostic use only. Do not pipette by mouth. Handle laboratory reagents in accordance with Good Laboratory Practice. May be harmful by ingestion. May cause irritation. Avoid contact with skin, inhalation and ingestion. This product contains 0.09% sodium azide, which is toxic to fish. Sodium azide reacts with lead or copper plumbing to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
Risk phrases:	None
Safety phrases:	None

<p>HbA1c Level 1 & Level 2 Controls</p> <p>Warnings:</p> <p>Risk phrases:</p> <p>Safety phrases:</p>	<p>For <i>in vitro</i> diagnostic use only. Do not pipette by mouth. Handle laboratory reagents in accordance with Good Laboratory Practice.</p> <p>Avoid contact with skin, avoid inhalation and ingestion.</p> <p>This product is human based and may be considered a biohazard and should be handled cautiously as a hazardous material. Each donor unit used in the preparation of this product was tested by a United States FDA approved method for the presence of the antibody to HIV 1 & 2 as well as for Hepatitis B surface antigen and HCV and found to be negative (was not repeatedly reactive). Because no test method can offer complete assurance that human T-lymphotropic virus types III (HIV), hepatitis B virus, or other infectious agents are absent, this product should be handled at the Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen in the United States Centres for Disease Control/National Institutes of Health manual ' Biosafety in Microbiological and Biomedical Laboratories,' 1984.</p> <p>None</p> <p>None</p>
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Commercial product name:	HbA1c Control Set
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4. First aid measures	
<p>Reconstitution Fluid</p> <p>Emergency First Aid:</p> <p>Inhalation:</p> <p>Ingestion:</p> <p>Skin Contact:</p> <p>Eye Contact:</p>	<p>Call a physician immediately. Arrange for transport to the nearest ER (emergency room).</p> <p>While awaiting the physician or transport to the ER:</p> <p>If it occurs move patient to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.</p> <p>If the patient is conscious, wash out mouth with water, give one or two glasses of water or milk to dilute immediately. Get immediate medical attention.</p> <p>Take off all contaminated clothing immediately. Wash off with soap and plenty of water. Wash contaminated clothing before re-use.</p> <p>Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Transport to hospital for further medical attention.</p>
<p>HbA1c Level 1 & Level 2 Controls</p> <p>Emergency First Aid:</p> <p>Inhalation:</p> <p>Ingestion:</p> <p>Skin Contact:</p>	<p>Call a physician immediately. Arrange for transport to the nearest ER (emergency room).</p> <p>While awaiting the physician or transport to the ER:</p> <p>If it occurs move patient to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.</p> <p>If the patient is conscious, wash out mouth with water, give one or two glasses of water or milk to dilute immediately. Transport to hospital for further medical attention.</p> <p>Remove any contaminated clothing. Wash off soap and water. Wash contaminated clothing before re-use.</p>

Revision: C
Date: June 2005

Eye Contact:	In case of eye contact immediately flush eyes with copious amounts of water for at least 15 – 20 minutes. Transport to see an ophthalmologist.
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Commercial product name:	HbA1c Control Set
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5. Fire-fighting measures	
Reconstitution Fluid & HbA1c Level 1 & Level 2 Control	
Flash point:	None
Flammable limits:	Not applicable
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	
Reconstitution Fluid 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
HbA1c Level 1 & Level 2 Control After spillage:	Sweep up, avoiding dust and place in a biohazard container. Wipe up area with a damp paper towel and discard in a biohazard container. Wipe up area with a damp paper towel and discard in a biohazard container. Disinfect spill area with a 10% bleach solution. 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

Commercial product name:	HbA1c Control Set
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7. Handling and storage	
Reconstitution Fluid	

Revision: C
Date: June 2005

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
HbA1c Level 1 & Level 2 Control	
7.1 Handling:	Wash thoroughly after handling. Do not use if skin is cut or scratched. Avoid contact with eyes, skin and clothing. Handle as a human serum sample. Do not breathe dust.
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

Reconstitution Fluid & HbA1c Level 1 & Level 2 Control	
MEL/OES	Not determined
Respiratory protection:	None
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

Reconstitution Fluid	
Physical state:	Liquid
Colour:	Clear, colourless
Odour:	Not determined
pH value:	Not determined
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

Commercial product name:	HbA1c Control Set
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9. Physical and chemical properties

Revision: C
Date: June 2005

HbA1c Level 1 & Level 2 Control	
Physical state:	Lyophilised powder
Colour:	Reddish - brown
Odour:	Not determined
pH value:	Not applicable
Boiling point	Not applicable
Melting point:	Not determined
Oxidising properties:	Not determined
Ignition temperature	Not determined
Explosion limits:	Not determined
Density:	Not determined
Solubility in water:	Soluble

10. Stability and reactivity	
Reconstituion Fluid	
Stability:	Stable
Conditions to avoid:	None determined
Substances to avoid:	Avoid contact with metals (aluminium, mercury, copper, lead, zinc) and acids
Hazardous decomposition products:	Sodium azide can react with heavy metals to form explosive azides
HbA1c Level 1 & Level 2	
Stability:	Stable
Conditions to avoid:	Avoid excessive heat which may cause product decomposition
Substances to avoid:	None determined
Hazardous decomposition products:	Thermal decomposition may yield oxides of carbon and nitrogen

11. Toxicological information:	
Reconstitution Fluid	
LD50 oral	LD50 oral rat: 27mg/kg LD50 dermal rabbit: 20mg/kg

Revision: C
Date: June 2005

LD50 intra-peritoneal	Not determined
LD50 skin	Not determined
LC50 inhalation	Not determined
Toxicological information: Chronic effects of overexposure: Carcinogen or suspended carcinogen: Medical conditions aggravated by exposure: Acute toxicity: Inhalation: Ingestion: Skin contact: Eye contact: Acute toxicity values:	Not thoroughly investigated None currently known. None of the components are listed as a carcinogen or suspected carcinogen. None currently known. Inhalation of mists may cause respiratory irritation and possible systemic effects similar to ingestion. Ingestion of sodium azide has been reported to cause shortness of breath, nausea, vomiting, restlessness, diarrhea, lowering of blood pressure (hypotension), and collapse. Rated highly toxic in animals. May cause mild irritation. Prolonged and extensive skin contact may result in absorption with systemic symptoms similar to ingestion. May cause irritation. LD50 oral rat: 27mg/kg LD50 dermal rabbit: 20mg/kg

11. Toxicological information:	
HbA1c Level 1 & Level 2 Control	
LD50 oral	Not determined
LD50 intraperitoneal	Not determined
LD50 skin	Not determined
LC50 inhalation	Not determined

Revision: C
Date: June 2005

Toxicological information:	Not thoroughly investigated
Chronic effects of overexposure:	None currently known.
Carcinogen or suspended carcinogen:	None of the components are listed as a carcinogen or suspected carcinogen.
Medical conditions aggravated by exposure:	None currently known.
Acute toxicity:	
Inhalation:	Inhalation of dust may cause minor respiratory discomfort.
Ingestion:	Contains human serum or other human source material. May cause gastrointestinal irritation and other adverse effects.
Skin contact:	Contact may cause mild irritation.
Eye contact:	May cause irritation.
Acute toxicity values:	Not applicable

12. Ecological information	
Reconstitution Fluid	
Water hazard class:	Data not yet available
	Ecological effects of this mixture have not been determined. The LC50 for sodium azide in Daphnia Pulex is reported to be 4.2 mg/L/96 hr @ 15°C and in Rainbow Trout to be 0.8 – 1.6 mg/L/96 hr @ 13°C, Wt 1.4 g.
HbA1c Level 1 & Level 2 Control	
Water hazard class:	Data not yet available
	Ecological effects of this mixture have not been determined.

Commercial product name:	HbA1c Control Set
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13. Disposal	
Reconstitution Fluid	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 This product contains sodium azide. Sodium azide may build up and form metal azides with copper or lead plumbing. This may produce a potential explosion hazard. See ' Safety Management No. CDC-22 (United States Center for Disease Control) Decontamination of Laboratory Sink Drains to remove Azide Salts'.
	Refer to Section 6.
HbA1c Level 1 & Level 2 Control	Each disposal facility must determine proper disposal methods of the

Revision: C
Date: June 2005

substance or preparation and any contaminated packaging to comply with
Local and National Environmental Regulations
Refer to Section 6.

14. Transport Information

Reconstitution Fluid, HbA1c Level 1 Control & HbA1c Level 2 Control

Proper shipping name: Not regulated

Technical name:

UN number: N/A

Hazard class and packaging group: Not regulated

Label(s): N/A

Packing Instruction (Passenger Aircraft): N/A

Packing Instruction (Cargo Aircraft): N/A

Unit volume: Reconstitution Fluid - 2 mL plastic

HbA1c Level 1 & Level 2 Control – 0.25 mL before lyophilisation

Primary container type: Reconstitution Fluid - 5 mL plastic, LD polyethylene

HbA1c Level 1 & Level 2 Control - 1 mL glass

Sales unit: Reconstitution Fluid – 1 bottle / kit

HbA1c Level 1 Control – 2 bottles / kit

HbA1c Level 2 Control – 2 bottles / kit

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

Commercial product name:	HbA1c Control Set
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15. Regulatory information	
Reconstitution Fluid	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 Level 1 & Level 2 Control	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.

Revision: C
Date: June 2005