

1. Information of the substance/preparation and of the company	
1.1 Commercial product name	HbA1c Calibrator Set
Cat. No.	KG3444
1.2. Company	<b>BGT BioGenTechnologies GmbH</b> Von-Langen-Weg 10 D-48565 Steinfurt Tel.: 02551/4090 Fax.: 02551/1298
1.3. In Emergencies	Tel.: 02551/4090

2. Composition / Hazardous Ingredients	
<b>Calibrator Level 1</b>	Sodium Hydroxide - 0.4%  Octylphenoxy polyethoxyethanol (Triton X-100) - 2.5%
Classification:	No hazardous chemicals as classified by CHIP 3
<b>Calibrator Levels 2-6</b>	Contains no hazardous substances in reportable quantities
Classification:	No hazardous chemicals as classified by CHIP 3

3. Hazards identification	
<b>Calibrator 1</b>  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 irritation to the eyes, respiratory system and skin. Avoid contact with skin, inhalation and ingestion.  None  None
<b>Calibrators 2 - 6</b>  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, inhalation and ingestion.  None  None

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<b>4. First aid measures for Calibrator Level 1</b>	
Emergency First Aid:	Call a physician immediately. Arrange for transport to the nearest ER (emergency room).  <b>While awaiting the physician or transport to the ER:</b>
Inhalation:	If it occurs move patient to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.
Ingestion:	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 all 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.

<b>4. First aid measures for Calibrator Level 2 - 6</b>	
Emergency First Aid:	Call a physician immediately. Arrange for transport to the nearest ER (emergency room).  <b>While awaiting the physician or transport to the ER:</b>
Inhalation:	If it occurs move patient to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.
Ingestion:	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.
Skin Contact:	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Wash contaminated clothing before re-use.
Eye Contact:	In case of eye contact immediately flush eyes with copious amounts of water for at least 15 – 20 minutes. Transport to hospital for further medical attention.

<b>5. Fire-fighting measures for Calibrators 1 - 6</b>	
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

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<b>6. Accidental release measures</b>
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<b>Calibrator Level 1</b> After spillage:	Appropriate Personal Protective Equipment should be worn, e.g. laboratory coat, gloves, safety glasses and mask.  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.  Ventilate area and wash spill site after material pick up is complete.
Absorbent material:	No restriction
<b>Calibrator Level 2 - 6</b> After spillage:	Appropriate Personal Protective Equipment should be worn, e.g. laboratory coat, gloves, safety glasses and mask.  Take up with absorbent material and place in a suitable container.  Wipe up area with a damp paper towel and discard.  Ventilate area and wash spill site after material pick up is complete
Absorbent material:	No restriction

<b>7. Handling and storage for Calibrators 1 - 6</b>	
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

<b>8. Exposure controls/personal protection</b>	
<b>Calibrator Level 1 - 6</b>	
MEL/OES	Not determined
Respiratory protection:	None required
Ventilation:	General room ventilation
Eye protection:	Protective glasses
Hand protection:	Standard laboratory rubber or latex gloves.
Skin protection:	A laboratory coat or apron is recommended.

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<b>9. Physical and chemical properties</b>	
<b>Calibrator Level 1</b>	
Physical state:	Liquid
Colour:	Dark Green 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
<b>Calibrator Level 2 - 6</b>	
Physical state:	Liquid
Colour:	Clear, colourless to yellow, aqueous solution
Odour:	No odour
pH value:	3.0
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

<b>10. Stability and reactivity</b>	
<b>Calibrator Level 1</b>	
Stability:	Stable
Conditions to avoid:	Avoid excessive heat
Substances to avoid:	Avoid strong acids and metals
Hazardous decomposition products:	None determined
<b>Calibrator Levels 2 - 6</b>	
Stability:	Stable
Conditions to avoid:	None determined
Substances to avoid:	None determined
Hazardous decomposition products:	None determined

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<b>11. Toxicological information:</b>	
<b>Calibrator Level 1</b>	
LD50 oral	LD50 oral rat: Sodium hydroxide 140 - 340 mg/kg Octyl Phenoxy Polyethoxy Ethanol 5 gm/kg
LD50 intra-peritoneal	Not determined
LD50 skin	Not determined
LC50 inhalation	Not determined
<b>Toxicological information:</b>	Not thoroughly investigated
Chronic effects of overexposure:	Repeated contact with sodium hydroxide solutions may cause dermatitis.
Carcinogen or suspected carcinogen:	None of the components are listed as a carcinogen or suspected carcinogen.
Medical conditions aggravated by exposure:	Pre-existing skin diseases and conditions
<b>Acute toxicity:</b>	
Inhalation:	Inhalation of mists may cause membrane and respiratory irritation.
Ingestion:	Swallowing may cause gastrointestinal irritation.
Skin contact:	Contact may cause irritation with redness, pain and swelling.
Eye contact:	Contact may cause irritation with possibly burns on prolonged contact.
Acute toxicity values:	LD50 oral rat: Sodium hydroxide 140 – 340 mg/kg Octyl Phenoxy Polyethoxy Ethanol 5 gm/kg
<b>Calibrator Level 2 - 6</b>	
LD50 oral	Not determined
LD50 intraperitoneal	Not determined
LD50 skin	Not determined
LC50 inhalation	Not determined
<b>Toxicological information:</b>	Not thoroughly investigated
Chronic effects of overexposure:	None currently known
Carcinogen or suspected carcinogen:	None of the components are listed as a carcinogen or suspected carcinogen.
Medical conditions aggravated by exposure:	None currently known.
<b>Acute toxicity:</b>	
Inhalation:	Inhalation of mists may cause membrane and respiratory irritation.
Ingestion:	Swallowing may cause gastrointestinal irritation.
Skin contact:	Contact may cause mild irritation, particularly on prolonged or repeated contact.
Eye contact:	May cause mild irritation.
Acute toxicity values:	Not applicable
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<b>12. Ecological information</b>	
<b>Calibrator Level 1</b>	
Water hazard class:	Data not yet available
	Ecological effects of this mixture have not been determined. This product contains 2.5% of a surfactant, Triton X-100 which has a reported TL50 for bluegill sunfish of 12 mg/L/96hr static.
<b>Calibrator Level 2 - 6</b>	
Water hazard class:	Data not yet available
	Ecological effects of this mixture have not been determined.

<b>13. Disposal</b>	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 Refer to Section 6.
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<b>14. Transport Information</b>			
<b>Calibrator Level 1</b>			
Proper shipping name: Sodium hydroxide solution			
Technical Name:			
UN number: UN1824			
Hazard class and packaging group: 8, III			
Label(s): Corrosive			
Packing Instruction (Passenger Aircraft): LATA 819 (5 L max, 2.5 L max inner pkg)			
Packing Instruction (Cargo Aircraft): LATA 821 (60 L max, 5 L max inner pkg)			
Unit volume: 8 mL			
Primary container type: 15 mL Plastic, HD polyethylene			
Sales Unit: 1 bottle / kit			
<b>Calibrator Level 2 - 6</b>			
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: 2 mL			
Primary container type: 7.5 mL Plastic, HD polyethylene			
Sales Unit: 1 of each level / 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

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<b>15. Regulatory information</b>	
<b>Calibrator 1</b>	This product contains no hazardous chemicals in reportable quantities according to CHIP 3.

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Hazard symbol:	None
Risk phrases:	None
Safety phrases:	None
Precautions:	See Section 3
<b>Calibrators 2 - 6</b>	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

<b>16. Other information</b>	
	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.