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

1.1 Product identifier

- Product Name: HbA1c

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

The sets are designed for Health Service laboratories for determination of HbA1c concentration in serum and plasma. The mixture is intended for professional use.

1.3 Details of the supplier of the safety data sheet

- Name of Manufacturer: Arena BioScien, SEA
- Address of Manufacturer: Block 5, Street 9 Ismailia free zone. Ismailia- Egypt
- Telephone: +202 21813500/ +201113102057
- Email: admin@arenabioscientific.com

SECTION 2 Hazards identification

2.1 Classification of the mixture

The kit HbA1c is not classified as dangerous according to EU Directives 1999/45/EC as amended

2.2 Label elements

None

S 25 Avoid contact with eyes.

SECTION 3 Composition/information on ingredients

3.1 Substances

The reagents contain the following hazardous substances:

Substance name	Content (% of weight)	CAS number	EC number	Classification according to (EC) No. 67/548 EEC	Classification according to (EC) No. 1272/2008
Sodium azide*	< 0.1	26628-22-8	247-852-1	T+; N; R 28-32-50/53; S 28-45-60-61	Acute Tox. 1, Aquatic Acute 1, Aquatic Chronic 1; H300, H400, H410; P273, P501, EUH032

*) Substance with exposure limits (exposure limits are listed in Chapter 8.1) For a full text of R-phrases , S-phrases, H-phrases and P-phrases see Section 16.

SECTION 4 First aid measures

4.1 General advice

When working with the mixture, take care of personal hygiene and prevent contamination of work clothing and skin. If you have any doubts or when symptoms persist, seek medical attention.

Exposure by inhalation

Discontinue the exposure, remove casualty to fresh air, keep at rest and seek medical advice.

Exposure by contact with skin

Take off all contaminated clothing. After contact with skin, wash immediately with soap and water.

Exposure by contact with eyes

Rinse an open eye (hold eyelids with fingers) with plenty of water for about 15 minutes, transfer casualty to a specialist.

Exposure by ingestion

Rinse mouth with water, drink 1/2 l of lukewarm water, seek medical attention immediately, do not induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

None

4.3 Indication of any immediate medical attention and special treatment needed

No data avealible

SECTION 5 Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media

The mixture is not flammable, the measure should be adapted to burning substances in the surrounding area.

Unsuitable extinguishing media

None known.

5.2 Specific hazards

None

5.3 Special protective equipment for fire-fighters

Protective clothing, breathing apparatus.

SECTION 6 Accidental release measures

6.1 Personal precautions

Use personal protective equipment, see item 8. Observe the principles of work safety in chemical laboratories. Do not eat, drink or smoke.

6.2 Environmental precautions

Do not discharge into the drains, surface waters, groundwater.

6.3 Methods for cleaning up

Absorb spilled agent with a suitable inert material (sand, earth, vapex) and store contaminated material in containers for collection of hazardous waste. For waste disposal see item 13. Sweep solid reagent and store in containers for collection of hazardous waste. For waste disposal see item 13.

SECTION 7 Handling and storage

7.1 Handling

Observe the principles of work in laboratory. Observe the normal operating procedures for handling chemical substances and mixtures. Do not eat, drink or smoke. Use personal protective equipment, see item 8.

7.2 Storage

Store in tightly closed containers at a temperature between +2°C and +8°C.

7.3 Specific use

The kit is designed for in vitro diagnostic devices.

SECTION 8 Exposure controls/personal protection

8.1 Control parameters

- There are no recommended or established controls for this product.

8.2 Exposure controls

- Eyewash bottles should be available.
- Engineering controls should be provided to prevent the need for ventilation.
- No respiratory protection is needed if ventilation/extraction is adequate, otherwise wear approved dust mask, NIOSH N95 (US) or type FFP1 (EN143) dust masks.
- Wear protective gloves. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and standard EN 374.
- Wear safety glasses approved to standard for ANSI Z87 or EN 166.

SECTION 8 Exposure controls/personal protection (continued…)

- Wear suitable protective clothing in accordance with good chemical hygiene practices.


Gloves


Safety Glasses


Lab Coat

SECTION 9 Physical and chemical properties

Reagent 1

a. Appearance .... white liquid
b. Odour..... ..... odourless
c. Odour Threshold .... no data available d. pH (při 20°C) .... 8.0 - 8.3
e. Melting point / freezing point .... no data available
f. Initial boiling point and boiling range (°C) ..... no data available
g. Flash point (°C) .... no data available
h. Evaporation rate .... no data available
i. Flammability (solid, gas)..... ..... no data available
j. Upper/lower flammability or explosive limits ..... no data available
k. Vapour pressure (hPa) .... no data available
l. Vapour density .... no data available
m. Relative density (kg.m-3) .... no data available n. Water solubility .... no data available
o. Partition coefficient: n- octanol/water ..... no data available
p. Autoignition temperature (°C) .... no data available
q. Decomposition temperature (°C) .... no data available
r. Viscosity .... no data available
s. Explosive properties .... no data available
t. Oxidizing properties .... no data available **Reagent 2**
a. Appearance .... Clear colorless liquide
b. Odour..... ..... odourless
c. Odour Threshold .... no data available
d. pH (při 20°C) 5.4-6.2
e. Melting point / freezing point .... no data available
f. Initial boiling point and boiling range (°C) ..... no data available
g. Flash point (°C) .... no data available
h. Evaporation rate .... no data available
i. Flammability (solid, gas)..... ..... no data available
j. Upper/lower flammability or explosive limits ..... no data available
k. Vapour pressure (hPa) .... no data available
l. Vapour density .... no data available
m. Relative density (kg.m-3) .... no data available n. Water solubility .... no data available
o. Partition coefficient: n- octanol/water ..... no data available
p. Autoignition temperature (°C) .... no data available
q. Decomposition temperature (°C) .... no data available
r. Viscosity .... no data available
s. Explosive properties .... no data available
t. Oxidizing properties .... no data available **Reagent 3**
a. Appearance .... Clear colorless liquide
b. Odour..... ..... odourless
c. Odour Threshold .... no data available

d. pH (při 20°C) 5.4-6.2
e. Melting point / freezing point .... no data available
f. Initial boiling point and boiling range (°C) ..... no data available
g. Flash point (°C) .... no data available
h. Evaporation rate .... no data available
i. Flammability (solid, gas)..... ..... no data available
j. Upper/lower flammability or explosive limits ..... no data available
k. Vapour pressure (hPa) .... no data available
l. Vapour density .... no data available m. Relative density (kg.m-3) .... no data available n. Water solubility .... no data available
o. Partition coefficient: n- octanol/water ..... no data available
p. Autoignition temperature (°C) .... no data available
q. Decomposition temperature (°C) .... no data available
r. Viscosity .... no data available
s. Explosive properties .... no data available
t. Oxidizing properties .... no data available

SECTION 10 Stability and reactivity

Under normal conditions of use and storage the mixture is stable.

10.1 Reactivity
No data available
10.2 Chemical stability
No data available
10.3 Possibility of hazardous reactions
No data available
10.4 Conditions to avoid
Avoid exposure to heat of solar radiation
10.5 Incompatible material
Heavy Metals, strong oxidizing agents and strong acids
10.6 Hazardous decomposition products
Nitrogen oxide and carbon

SECTION 11 Toxicological information

11.1 Acute toxicity
Human oral LD50 (g.kg-1) ..... not applicable
Rat oral LD50 (g.kg-1) ..... not applicable
Rat inhalation LD50 (g.kg-1) ..... not applicable
Rat inhalation TLS (g.kg-1) ..... not applicable
11.2 Skin corrosion/irritation
Not applicable.
11.3 Serious eye damage/eye irritation
Not applicable.
11.4 Respiratory or skin sensitization
Not applicable.
11.5 Germ cell mutagenicity
Not applicable.
11.6 Carcinogenicity
Not applicable.
11.7 Reproductive toxicity
Not applicable.
11.8 Specific target organ toxicity

- single exposure
Not applicable.

11.9 Specific target organ toxicity
- repeated exposure
Not applicable.

11.10Aspiration hazard
Not applicable

SECTION 12 Ecological information

12.1 Toxicity
- Quantitative data on the toxic effects of this product is not available.

12.2 Persistence and degradability
- The test kit contains plastic and other components that are not readily degradable.

12.3 Bioaccumulation Potential
- No information available

12.4 Mobility in soil
- No information available

12.5 Results of PBT and vPvB assessment
- Not a PBT according to REACH Annex XIII
- PBT/vPvB assessment not available

12.6 Other Adverse Effects
- To the best of our knowledge, the properties of this material have not been fully evaluated.
- On available data, substance is not harmful to the environment.

SECTION 13 Disposal considerations

13.1 Waste treatment methods
Dispose of in compliance with applicable regulations for hazardous waste management. Incinerate residues of the mixture in a hazardous waste incinerator. Contaminated packaging must be treated as hazardous waste. Dispose of by incinerating in a hazardous waste incinerator

SECTION 14 Transport information

14.1 UN Number
- Not classified as hazardous for transport

14.2 UN Proper Shipping Name
- Not applicable

14.3 Transport hazard class(es)
- Not applicable

14.4 Packing group
- Not applicable

14.5 Environmental hazards
- Not Classified

14.6 Special precautions for user
- Not Classified

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code
- Not Classified

14.8 Domestic Surface Transport (US DOT)
- Proper Shipping Name: Not applicable
- DOT UN No.: Not applicable
- DOT Hazard Class: Not applicable

SECTION 14 Transport information (continued…)

- DOT Packing Group: Not applicable

14.9 International Road/Rail (ADR/RID)
- Proper Shipping Name: Not applicable
- ADR UN No.: Not applicable
- ADR Hazard Class: Not applicable
- ADR Packing Group: Not applicable
- Tunnel Code: Not applicable

14.10 Ocean/Sea (IMO/IMDG)
- Proper Shipping Name: Not applicable
- IMDG UN No.: Not applicable
- IMDG Hazard Class: Not applicable
- IMDG Packing Group: Not applicable

14.11 Air (ICAO/IATA)
- Proper Shipping Name: Not applicable
- ICAO Un No.: Not applicable
- ICAO Hazard Class: Not applicable
- ICAO Packing Group: Not applicable

SECTION 15 Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- This Safety Data Sheet is provided in compliance with the EC Directive 1907/2006- 453/2010, WHMIS 2015 requirements as specified in the Hazardous Products Act (HPA) and the Hazardous Products Regulations (HPR), and with the OSHA Hazard Communication Standard 29 CFR 1910.1200.
- Regulation (EC) No. 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation) applies in Europe.

SECTION 16 Other information

Date of Preparation: September 2019
Revision: Rev. 0
Replaces: New issue
This document is believed to be correct, but does not purport to be all inclusive and shall be used only as a guide. Arena BioScien Manufacturers, SEA. Shall not be held liable for any damage resulting from handling or from contact with the above product. These suggestions should not be confused with state, municipal or insurance requirements, and constitute NO WARRANTY.