MATERIAL SAFETY DATA SHEET

According with Regulation (EC) No1907/2006 and (EC) No 1272/2008

QUALITY MANAGEMENT **Version 1.1 Revision date: 06/06/2025**

SECTION 1:Identification of the Substance/Mixture and of the Company/Undertaking	
Trade name	Blood Glucose Monitoring System
Catalog number	Blood Glucose Monitoring System(GHP-101ProSK) composed of: Blood Glucose Test Meter: GOH-101Pro/GOH-101/GOH-201 Blood Glucose Test Strips: C902005-10
Chemical Family/Use of the substance preparation	Blood Glucose Monitoring System(GHP-101ProSK) is an automatic *in vitro* monitoring system for quantitative detection of glucose concentration in fresh capillary whole blood or venous whole blood. The system is intended for self-testing by people with diabetes or people suspected of having diabetes at home, and for near-patient testing by healthcare professionals in clinical settings. The system is only used for the monitoring of blood glucose levels and the preliminary screening of blood glucose abnormalities, and is not suitable for the diagnosis of diabetes.
Formula	Proprietary mixture
Shipping name	Not applicable
Dot hazard classification	Not applicable
Manufacturer	Assure Tech. (Hangzhou) Co., Ltd Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, 310011 Zhejiang, P.R. China Website: www.diareagent.com
Contact	contact@diareagent.com
Emergency telephone	Phone: #86-571-81022690 Fax: #86-571-88865920 Phone number is available during office hours as follows: Mon – Fri 8: 30AM – 5:30 PM
SECTION 2: Hazards Identification	
Classification of the substance or mixture	**Classification according to Regulation (EC) No 1272/2008** The product is not classified according to the CLP regulation
Label elements	**Labelling according to Regulation (EC) No 1272/2008** The product is not classified according to the CLP regulation
Other Hazards	Our products do not contain related or similar endocrine disrupting substances in accordance with (EU) 2020/878 ANNEX II and (EC) No. 1907/2006 ANNEX XIV. No particular hazards if test is used according to the instructions. The product contains chemicals and materials of animal origin. Although the risk of infection is rated as extremely unlikely, a direct contact should be avoided.

SECTION 3: Composition/Information on Ingredients

This product is a mixture In vitro diagnostics medical device.

kit Components:

- 1 Blood Glucose Test Meter (REF:GOH-101Pro/GOH-101/GOH-201) with 2 AAA Batteries
- 1 Lancing Device
- 1 User's Manual
- 1 Quick Reference Guide
- 1 Carrying Case
- 1 Warranty Card
- 1 Blood Glucose Test Strips(REF:C902005-10)*
- 1 Insert package
- 10 Sterile Lancets

*Each test strip contains reactive and non-reactive chemicals. These chemicals are: glucose oxidase < 25 IU, mediator < 300 µg, buffer, and non-reactive ingredient.

Hazardous Components:

The product is no hazardous component according to the CLP regulation ((EC) No 1272/2008).

SECTION 4: First-aid Measures

If used according to the instructions the described scenarios are extremely unlikely.

After skin contact	Not applicable

After eye contact	Not applicable
After ingestion	Not applicable
After inhalation	Not applicable
SECTION 5: Firefighting Measures	
Flash point	Not applicable
Flammable limits	Not applicable
Autoignition temperature	Not applicable
Extinguishing media	Suitable extinguishing media: Dry chemical, CO_2, water spray or alcohol-resistant foam. Unsuitable extinguishing media: Not known. If possible, run-off water should be prevented from entering bodies of water or other environmentally sensitive areas.
Special fire combustion products	None
Protective equipment for firefighter	As in any fire, wear self-contained breathing apparatus and full protective gear.
SECTION 6: Accidental Release Measures	
Personal safety precaution	Not applicable
Spill and leak procedures	Large spills or leak of this product are unlikely.
Environmental precautions	No environmental hazard is anticipated provided that the material is handled and disposed of with due care. Generally, a release to the environment should be avoided.
SECTION 7: Handling and Storage	
Precaution to be taken in handling and storage	Storage conditions of Blood Glucose Test Meter: -5~45°C(23~113°F); ≤90%RH Storage conditions of Blood Glucose Test Strips: 2-30°C(35.6~86°F); ≤90%RH
Requirements to be met by storage conditions	Blood Glucose Test Meter: Do not get water or other liquids on or inside the meter. Keep the meter dry and avoid exposing it to extreme in temperatures and humidity. Do not store the meter near bleach or cleaners that contain bleach. Blood Glucose Test Strips: Keep out of direct sunlight. Do not freeze. Do not store or use test strips in a humid place such as a bathroom. Do not store the test strips near bleach or cleaners that contain bleach. Test strips must be stored in the original vial with the cap tightly closed.
Other precautions/special hazards	No information available.
SECTION 8: Exposure Controls/Personal Protection	
The product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.	
Exposure limits	No information available.
Derived no effect level (DNEL)	No information available.
Predicted no effect concentration (PNEC)	No information available.
Skin and body protection	Laboratory clothes if needed
Eye protection	Protective Lab Glasses if needed
Hand protection	Impervious Gloves (nitrile, rubber, latex or equivalent)if needed
Respiratory protection	Not applicable
Hygiene measures	Handle in accordance with good industrial hygiene and safety practice.
Environmental exposure controls	No special environmental controls are required. Disposal of test according to section 13.
SECTION 9: Physical and Chemical Properties	
Physical State	Solid material

Color	Blood Glucose Test Meter: White Blood Glucose Test Strips: Purple
Odor	Odorless
Flash point	Not determined
Self-igniting	Not determined
pH-value at 20°C	Not applicable for solid materials
Melting/freezing point	Solid materials: Plastics decomposition at ~300°C
Vapor pressure	No information available.
Vapor density	No information available.
Specific Gravity	No information available.
Water solubility	No information available.
Solubility in other solvents VALUE	No information available.
SECTION 10: Stability and Reactivity	
Chemical stability	The product is stable. Hazardous degradation products are not known, if the storage conditions are observed. Plastic components: Hazardous decomposition products during burning possible.
Conditions to avoid	Extreme of temperature and direct sunlight.
Incompatible materials	Acids.
Hazardous decomposition products	None under normal use conditions.
SECTION 11: Toxicological Information	
Product information	Product does not present an acute toxicity hazard based on known or supplied information.
Serious eye damage/irritation	No information available.
Skin corrosion/irritation	No information available.
Acute toxicity	Product does not present an acute toxicity hazard based on known or supplied information.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
Summary of evaluation of the CMR properties	No information available.
Specific target organ systemic toxicity (single exposure)	No information available.
Specific target organ systemic toxicity (repeated exposure)	No information available.
Aspiration hazard	No information available.
SECTION 12: Ecological Information	
Ecotoxicity effects	Contains no substances known to be hazardous to the environment or not degradable in waste water treatment plants.
Persistence and degradability	Generally, plastic materials are not biodegradable and should not be dumped into the environment.
Bioaccumulative potential	The potential of product components to accumulate in animal or plant systems is considered to be very limited.
Mobility in soil	No information available.
Results of PBT and vPvB assessment	No sufficient information available for assessment. To our knowledge this preparation contains no amounts of substances regarded as persistent, bioaccumulative and toxic (PBT) or substances that are considered to be very persistent and very bioaccumulative (vPvB) that need to be declared.
Other adverse effects	No information available.
SECTION 13: Disposal Considerations	
Waste from residues/unused products	In all cases disposal of tests should be in compliance with federal and local regulations. The potentially infectious character of the sample material should be taken into consideration before disposal. Observe

	regulations for proper disposal of such materials. Frequently tests can be disposed of with the regular garbage. If in doubt, we recommend to contact the relevant authorities and/or an approved waste-disposal company for information to ensure compliance.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for disposal. Non-contaminated packaging materials can be recycled.
SECTION 14: Transport Information	
Identification	Not applicable.
Special provision for transport	According to the 66th edition 2025 of IATA Dangerous Goods Regulation, the products are not dangerous, poisonous, harmful, corrosive flammable or explosive. They are not spiritual medicines, not anesthetic or narcotic, and cannot be used to make bio-chemical weapons. They are in sealed packages and conform to the export requirements by china customs and CAAC. The products is safe for transportation and not regulated by IATA DGR/IMDG.
SECTION 15: Regulatory Information	
Safety, health and environmental regulations/legislation specific for the substance or mixture	This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006, Regulation (EC) No 1272/2008 and (EU) 2020/878 Annex II.
Chemical safety assessment	For this product a chemical safety assessment has not been carried out
SECTION 16: Other Information	
The given information is based on the current state of knowledge but does not guaranty product performances under cannot be used as basis for legal disputes For further information please contact Assure Tech.	

Document History

Revision	Changes/Reason for changes	Released (date)
1.0	New document according to IVDR requirements	2024-08-30
1.1	For the packaging of Blood Glucose Monitoring System, add meter models GOH-101 and GOH-201	2025-06-06