

## MATERIAL SAFETY DATA SHEET

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

QUALITY MANAGEMENT

Version 1.0 Revision date: 08/30/2024

SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking	
Trade name	Blood Glucose Control Solution
Catalog number	C901095
Chemical Family/Use of the substance preparation	<p>The Blood Glucose Control Solution contains a known concentration of glucose. It is used to confirm that your C901005 Blood Glucose Test Strips and your Blood Glucose Test Meter are working together properly and that you are performing the test correctly. The control solution acts like blood when you apply it to a Blood Glucose Test Strips. Performing a control test lets you know the meter and test strips are working properly.</p> <p>Blood Glucose Monitoring System is an automatic <i>in vitro</i> monitoring system for quantitative detection of glucose concentration in fresh capillary 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.</p> <p>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.</p>
Formula	Proprietary mixture
Shipping name	Not applicable
Dot hazard classification	Not applicable
Manufacturer	<p>Assure Tech. (Hangzhou) Co., Ltd            Building 4, No. 1418-50, Moganshan Road, Gongshu District,            Hangzhou, 310011 Zhejiang, P.R. China            Website: <a href="http://www.diareagent.com">www.diareagent.com</a></p>
Contact	<a href="mailto:contact@diareagent.com">contact@diareagent.com</a>
Emergency telephone	<p>Phone: #86-571-81022690            Fax: #86-571-88865920            Phone number is available during office hours as follows:            Mon – Fri 8: 30AM – 5:30 PM</p>
SECTION 2: Hazards Identification	
Classification of the substance or mixture	<p><b>Classification according to Regulation (EC) No 1272/2008</b>            The product is not classified according to the CLP regulation</p>
Label elements	<p><b>Labelling according to Regulation (EC) No 1272/2008</b>            The product is not classified according to the CLP regulation</p>
Other Hazards	<p>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 less than 0.1% glucose or less than 0.2% glucose both with a low amount of preservatives. Although the risk of infection is rated as extremely unlikely, a direct contact should be avoided.</p>
SECTION 3: Composition/Information on Ingredients	
<p>This product is Glucose control Solution material. The control can be used to verify proper performance of Blood Glucose Test Strips or Blood Glucose Test Meter.</p> <p><b>kit Components:</b></p> <ul style="list-style-type: none"> <li>Control solution 1 contains less than 0.1% glucose(active ingredient)and Control solution 2 contains less than 0.2% glucose(active ingredient),both with preservatives in an aqueous based mixture.</li> <li>Package Insert.</li> </ul>	
<p><b>Hazardous Components:</b>            The product is no hazardous component according to the CLP regulation ((EC) No 1272/2008).</p>	
SECTION 4: First-aid Measures	
If used according to the instructions the described scenarios are extremely unlikely.	
After skin contact	<p>The control solution and possibly other kit components may cause slight irritations upon contact. Remove contaminated clothing. Wash affected area with plenty of water. If irritation or signs of toxicity</p>

	occur, seek medical attention.
<b>After eye contact</b>	The control solution and possibly other kit components may cause slight irritations upon contact. Remove from source of exposure. Wash with copious amounts of water (for appr. 15 min) with eyelid held open. If irritation or signs of irritation, pain or toxicity occur, seek medical attention.
<b>After ingestion</b>	If control solution has been ingested, rinse mouth with water provided the person is conscious. If irritation or signs of toxicity occur, seek medical attention.
<b>After inhalation</b>	Inhalation of any components of the product is extremely unlikely. If a component is inhaled and causes discomfort, remove exposed person from source of exposure and take outside to fresh air. If breathing is difficult, irritation or signs of toxicity occur, seek medical attention.
<b>SECTION 5: Firefighting Measures</b>	
<b>Flash point</b>	Not applicable
<b>Flammable limits</b>	Not applicable
<b>Autoignition temperature</b>	Not applicable
<b>Extinguishing media</b>	Suitable extinguishing media: Dry chemical, CO <sub>2</sub> , 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.
<b>Special fire combustion products</b>	None
<b>Protective equipment for firefighter</b>	As in any fire, wear self-contained breathing apparatus and full protective gear.
<b>SECTION 6: Accidental Release Measures</b>	
<b>Personal safety precaution</b>	Remove unprotected persons from source of exposure. Avoid contact with skin and eyes. Use universal precautions during clean-up procedures.
<b>Spill and leak procedures</b>	Large spills or leak of this kit are unlikely. Personnel who have received basic chemical safety training can generally handle small-scale releases. Wear protective garment (safety glasses, gloves, lab coat). Take up spills with absorbent paper; if necessary clean with disinfectant afterwards and dispose of in accordance with the local regulations (see section 13). Clean affected area with water afterwards.
<b>Environmental precautions</b>	No environmental hazard is anticipated if the material is handled and disposed of with due care. Generally, a release to the environment should be avoided.
<b>SECTION 7: Handling and Storage</b>	
<b>Precaution to be taken in handling and storage</b>	Store at 2-30°C
<b>Requirements to be met by storage conditions</b>	Store the control solution at temperature between 2-30°C and ≤90% relative humidity
<b>Other precautions/special hazards</b>	No information available.
<b>SECTION 8: Exposure Controls/Personal Protection</b>	
The product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.	
<b>Exposure limits</b>	No information available.
<b>Derived no effect level (DNEL)</b>	No information available.
<b>Predicted no effect concentration (PNEC)</b>	No information available.
<b>Skin and body protection</b>	No information available.
<b>Eye protection</b>	No information available.
<b>Hand protection</b>	Impervious Gloves (nitrile, rubber, latex or equivalent)
<b>Respiratory protection</b>	No information available.
<b>Hygiene measures</b>	Handle in accordance with good industrial hygiene and safety practice.
<b>Environmental exposure controls</b>	No special environmental controls are required. Disposal of test according to section 13.

SECTION 9: Physical and Chemical Properties	
Physical State	Liquid material
Color	Red
Odor	Odorless
Flash point	Not determined
Self-igniting	Not determined
pH-value at 20°C	About 7
Melting/freezing point	Do not freeze
Vapor pressure	≤90% relative humidity
Vapor density	Not applicable..
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.
Conditions to avoid	Extreme of temperature and direct sunlight.Do not freeze.
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	No information available. No adverse effects on the environment are expected.
Persistence and degradability	Generally, plastic materials are not biodegradable and should not be dumped into the environment.
Bioaccumulative potential	The potential of kit 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	No specifications required. In all cases disposal of tests should be in compliance with federal and

	<p>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.</p> <p>If in doubt, we recommend to contact the relevant authorities and/or an approved waste-disposal company for information to ensure compliance.</p>
<b>Contaminated packaging</b>	<p>Empty containers should be taken to an approved waste handling site for disposal.</p> <p>Non-contaminated packaging materials can be recycled.</p>
<b>SECTION 14: Transport Information</b>	
<b>Identification</b>	Not applicable.
<b>Special provision for transport</b>	<p>According to the 65<sup>th</sup> edition 2024 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.</p> <p>The products is safe for transportation and not regulated by IATA DGR/IMDG.</p>
<b>SECTION 15: Regulatory Information</b>	
<b>Safety, health and environmental regulations/legislation specific for the substance or mixture</b>	This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006, Regulation (EC) No 1272/2008 and (EU) 2020/878 Annex II.
<b>Chemical safety assessment</b>	For this product a chemical safety assessment has not been carried out
<b>SECTION 16: Other Information</b>	
<p>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</p> <p>For further information please contact Assure Tech.</p>	

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## Document History

Revision	Changes/Reason for changes	Released (date)
1.0	New document according to IVDR requirements	2024-08-30