



## SAFETY DATA SHEET

According with Regulation (EC) No 1907/2006

QUALITY MANAGEMENT

Version 1.0, DATE: 01/20/2021

SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking	
Trade name	COVID-19 Antigen Rapid Test Device
Catalog number	COV-S23
Chemical Family/Use of the substance preparation	In vitro diagnostic rapid test, it is intended to aid in the rapid differential diagnosis of SARS-CoV-2 viral nucleoprotein antigens from human nasopharyngeal secretions, nasal secretions and oropharyngeal secretions.
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
Contact	<a href="mailto:contact@diareagent.com">contact@diareagent.com</a>
Emergency telephone	Phone: #86-571-88868960 Fax: #86-571-88865920 Phone number is available during office hours as follows: Mon – Fri 8 :30 AM – 5:30 PM
SECTION 2: Hazards Identification	
Classification of the substance or mixture	<b>Classification according to Regulation (EC) No 1272/2008</b> The product is not classified according to the CLP regulation
Label elements	<b>Labelling according to Regulation (EC) No 1272/2008</b> The product is not classified according to the CLP regulation
Other Hazards	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	
<p>This product is a mixture in vitro diagnostics medical device.</p> <p><b>Kit Components:</b></p> <ul style="list-style-type: none"><li>● Test devices: Strips inside the housing contain small amounts of chemicals (proteins, surfactants, biological buffers, salts, carbohydrates, polymers, latex particles and preservative (sodium azide)) and small amounts of antibodies or antigens as active ingredients of the detection reaction, conjugated to latex particles or immobilised on the test line regions. The backing plate of each test strip is made of polyethylene. The membrane is nitrocellulose. The strip further contains adsorbent pads (cellulose), polyester and glass fiber.</li><li>● Extraction buffer Buffer components: Biological buffer, salts and surfactants. Preservatives: Sodium azide.</li><li>● Coated Aluminium Foil for single pouched test devices</li><li>● Individually packed swabs: The sterilized swab has the CE mark.</li><li>● Desiccant (SiO<sub>2</sub>)</li><li>● Package insert (paper)</li></ul>	

<ul style="list-style-type: none"> <li>● Extraction tube</li> <li>● Tube stand</li> </ul>	
<b>Hazardous Components:</b> The product is no hazardous component according to the CLP regulation ((EC) No 1272/2008). Although the substance sodium azide (CAS 26628-22-8) is rated as hazardous, they do not need to be declared as hazardous components in this formulation because of the extremely low concentration on the test strip and in the buffer solution (CAS 26628-22-8: <0.1%).	
<b>Chemical Names and Synonyms</b>	Not applicable
<b>Chemical Family</b>	Not applicable
<b>Formula</b>	Not applicable
<b>Shipping Name</b>	Not applicable
<b>Hazard Classification</b>	Not applicable
<b>SECTION 4: First-aid Measures</b>	
If used according to the instructions the described scenarios are extremely unlikely.	
<b>After skin contact</b>	The buffer 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 occur, seek medical attention.
<b>After eye contact</b>	The buffer 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 buffer solution, kit or test components have 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 kit 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 trains 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 provided that 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>	Keep containers tightly closed in a dry, cool and well-ventilated place.
<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>	Laboratory clothes
<b>Eye protection</b>	Protective Lab Glasses are recommended
<b>Hand protection</b>	Impervious Gloves (nitrile, rubber, latex or equivalent)
<b>Respiratory protection</b>	Mask
<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.
<b>SECTION 9: Physical and Chemical Properties</b>	
<b>Physical State</b>	Solid material Buffer solution: liquid
<b>Color</b>	White
<b>Odor</b>	Odorless
<b>Flash point</b>	Not determined
<b>Flammability</b>	Not determined
<b>pH-value at 20°C</b>	Not applicable for solid materials Buffer solution: $\approx 7$
<b>Melting/freezing point</b>	Solid materials: Plastics decomposition at $\sim 300^{\circ}\text{C}$ Buffer solution: $\approx 0^{\circ}\text{C}$ (do not freeze)
<b>Vapor pressure (20°C)</b>	Not applicable for solid components Buffer solution: $\sim 23\text{hPa}$ (similar to water)
<b>Vapor density</b>	Not applicable.
<b>Specific Gravity</b>	No information available.
<b>Water solubility</b>	No information available.

<b>Solubility in other solvents VALUE</b>	No information available.
<b>SECTION 10: Stability and Reactivity</b>	
<b>Reactivity</b>	Not known
<b>Chemical stability</b>	The product is stable. Hazardous degradation products are not known, if the storage conditions are observed. Plastic components: Hazardous decomposition products during burning possible.
<b>Conditions to avoid</b>	Extreme of temperature and direct sunlight.
<b>Incompatible materials</b>	Acids.
<b>Hazardous decomposition products</b>	None under normal use conditions.
<b>SECTION 11: Toxicological Information</b>	
<b>Product information</b>	Product does not present an acute toxicity hazard based on known or supplied information.
<b>Serious eye damage/irritation</b>	No information available.
<b>Skin corrosion/irritation</b>	No information available.
<b>Acute toxicity</b>	Product does not present an acute toxicity hazard based on known or supplied information. Sodium azide (pure substance): Oral LD50 (rat): 27mg/kg; dermal LD50 (rabbit): 20mg/kg
<b>Respiratory or skin sensitization</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Carcinogenicity</b>	No information available.
<b>Reproductive toxicity</b>	No information available.
<b>Summary of evaluation of the CMR properties</b>	No information available.
<b>Specific target organ systemic toxicity (single exposure)</b>	No information available.
<b>Specific target organ systemic toxicity (repeated exposure)</b>	No information available.
<b>Aspiration hazard</b>	No information available.
<b>SECTION 12: Ecological Information</b>	
<b>Ecotoxicity effects</b>	No information available. No adverse effects on the environment are expected. However, for sodium azide, following applies: Harmful to aquatic life with long lasting effects. In the present amounts (<0.1%) hazardous influences on the environment are to be unlikely as the concentrations of hazardous components are below the threshold values that would require labeling.
<b>Persistence and degradability</b>	Generally plastic materials are not biodegradable and should not be dumped into the environment.
<b>Bioaccumulative potential</b>	The potential of kit components to accumulate in animal or plant systems is considered to be very limited.
<b>Mobility in soil</b>	No information available.
<b>Results of PBT and vPvB assessment</b>	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.
<b>Other adverse effects</b>	No information available.

<b>SECTION 13: Disposal Considerations</b>	
<b>Waste from residues/unused products</b>	No specifications required. 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.
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for disposal. Non-contaminated packaging materials can be recycled.
<b>SECTION 14: Transport Information</b>	
<b>Identification</b>	Not applicable.
<b>Transport(ICA0/IATA)</b>	According to the 61st edition 2020 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.
<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.
<b>Chemical safety assessment</b>	For this product a chemical safety assessment has not been carried out.
<b>SECTION 16: Other Information</b>	
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.	