



MATERIAL SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

SECTION 1 — CHEMICAL PRODUCT AND COMPANY IDENTIFICATION


1.1 Product Identifier SARS-CoV-2 Antigen Rapid Qualitative Test		[WHMIS Classification] 	
REACH No. : This product is a mixture. REACH Registration Number see section 3.			
1.2 Product Use The SARS-Cov-2 Rapid Antigen Qualitative Test is an in vitro diagnostic rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid protein (N protein) in human swabs from individuals who are suspected of COVID-19 within the first five days of the onset of symptoms or with known or suspected exposure to SARS-Cov-2. This test is intended to be used at the point of care by healthcare workers or trained users to identify potentially infectious individuals in a population or congregated setting. When the test is used for individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection, the test should be used repeatedly, with at least 24-hours (and no more than 36 hours) between each test. SARS-CoV-2 nucleocapsid antigen is usually detectable in nasal samples during the acute phase of the infection. Positive results indicate the presence of viral antigens, but a clinical correlation with the patient's history and other diagnostic information is needed to determine the state of the infection. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the actual cause of disease. A negative result does not rule out an infection by the COVID-19 virus and should not be used as the sole basis for decisions about the treatment or patient management decisions including infection control. Negative results should be considered in a broader context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. Individuals who test negative and continue to experience COVID-like symptoms should seek follow-up care from their healthcare provider.			
Manufacturer's Name Xiamen Biotime Biotechnology Co., Ltd		Supplier's Name Xiamen Biotime Biotechnology Co., Ltd	
Street Address 2F/3F/4F/5F, No.188, Pingcheng South Road, Haicang Street, Haicang District, Xiamen City, Fujian Province, 361026, P. R. China.		Street Address 2F/3F/4F/5F, No.188, Pingcheng South Road, Haicang Street, Haicang District, Xiamen City, Fujian Province, 361026, P. R. China.	
City Xiamen	Province Fujian	City Xiamen	Province Fujian
Postal Code 361026	Emergency Telephone +86-592-6882386	Postal Code 361026	Emergency Telephone +86-592-6882386
Date MSDS Prepared 07/18/2022	MSDS Prepared By Xiamen Biotime Biotechnology Co., Ltd		Phone Number +86-592-6882386

SECTION 2 — HAZARDS IDENTIFICATION

Classification of the substance or mixture	
Skin sensitization (Category 1), H317	
Route of Entry <input type="checkbox"/> Skin Contact <input checked="" type="checkbox"/> Skin Absorption <input type="checkbox"/> Eye Contact <input type="checkbox"/> Inhalation <input type="checkbox"/> Ingestion	
[Emergency Overview] Transparent liquid. In contact with skin: Wash skin with water. In contact with eyes: Wash eyes with large amount of water; if you wear contact lenses, remove them and wash your eyes. Please seek medical attention immediately if swallowed. React violently with a strong oxidant and acid.	
[WHMIS Symbols] 	
[Potential Health Effects]	
Eye: None	
Skin: H317 May cause an allergic skin reaction.	
Inhalation: None	

Ingestion: None
Chronic Toxicity: None
Reproductive and Developmental Toxicity: None
Carcinogenicity: None
Medical Conditions Aggravated by Exposure: None

SECTION 3 — COMPOSITION/INFORMATION ON INGREDIENTS

Mixtures						
Component	%	CAS Number	Classification according to Regulation (EC) No 1272/2008	Labelling according Regulation (EC) No 1272/2008	Precautionary Statement Codes	Specific Conc. Limits, M-factors
Na ₂ HPO ₄ Disodium hydrogen phosphate	0.2123%	7558-79-4	NA	N/A	NA	NA
NaH ₂ PO ₄ Monosodium phosphate	0.0346%	7558-80-7	NA	N/A	NA	NA
NaCl Sodium chloride	0.85%	7647-14-5	NA	N/A	NA	NA
Tween-20	1.0%	9005-64-5	NA	N/A	NA	NA
Proclin 300	0.05%	55965-84-9	Acute toxicity, Oral (Category 4), H302 Acute toxicity, Inhalation (Category 4), H332 Skin corrosion (Sub-category 1B), H314 Serious eye damage (Category 1), H318 Skin sensitization (Category 1), H317 Short-term (acute) aquatic hazard (Category 1), H400 Long-term (chronic) aquatic hazard (Category 1), H410		P273, P280; P301+P312; P303+P361+P353; P304+ P340+P310; P304+P351+P338	Skin Corr. 1B; H314: C ≥ 0,6 % Skin Irrit. 2; H315: 0,06 % ≤ C < 0,6 % Eye Irrit. 2; H319: 0,06 % ≤ C < 0,6 % Skin Sens. 1; H317: C ≥ 0,0015 %
H ₂ O Water	97.9031%	9005-64-5	NA	N/A	N/A	NA

SECTION 4 — FIRST AID MEASURES

[Precautionary statement]
<p>P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.</p> <p>P302 + P352 IF ON SKIN: Wash with plenty of soap and water.</p> <p>P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.</p> <p>P363 Wash contaminated clothing before reuse.</p> <p>P501 Dispose of contents according to IFU</p>

Please continue on reverse side

[Optional, not required under WHMIS]

Product Identifier

SECTION 5 — FIRE FIGHTING MEASURES

Flammable <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		If yes, under which conditions? Water Foam Carbon dioxide (CO2) Dry powder	
Means of Extinction Extinguishing Media: Water, carbon dioxide, multipurpose dry chemical or halon-fire extinguisher.			
Flashpoint (°C) and Method		Upper Flammable Limit (% by volume)	Lower Flammable Limit (% by volume)
Autoignition Temperature (°C)		Explosion Data — Sensitivity to Impact	Explosion Data — Sensitivity to Static Discharge
Hazardous Combustion Products			
[NFPA]			

SECTION 6 — ACCIDENTAL RELEASE MEASURES

Leak and Spill Procedures To wipe use the paper. Wash hands.

SECTION 7 — HANDLING AND STORAGE

Handling Procedures and Equipment Normal Save
Storage Requirements Test Cartridge: 2-30°C Antigen extraction solution: 2-30°C

SECTION 8 — EXPOSURE CONTROL / PERSONAL PROTECTION

Exposure Limits <input type="checkbox"/> ACGIHLV <input type="checkbox"/> OSHA PEL <input type="checkbox"/> Other (specify)	
Specific Engineering Controls (such as ventilation, enclosed process) None	
Personal Protective Equipment None <input type="checkbox"/> Gloves <input type="checkbox"/> Respirator <input type="checkbox"/> Eye <input type="checkbox"/> Footwear <input type="checkbox"/> Clothing <input type="checkbox"/> Other	
If checked, please specify type	

[Optional, not required under WHMIS]

Physical State Liquid	Odour and Appearance clear, odorless, no precipitation, no flocculation or other insoluble matter.	Odour Threshold (ppm) Not applicable.
Specific Gravity Not available.	Vapour Density (air = 1) Not applicable	Vapour Pressure (mmHg) Nil
Evaporation Rate Nil	Boiling Point (°C) Not applicable.	Freezing Point (°C) Not applicable.
pH 7.2 ± 0.2	Coefficient of Water/Oil Distribution Not available.	[Solubility in Water] Not available.

Chemical Stability <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If no, under which conditions? Excessive heat, direct sunlight
Incompatibility with Other Substances <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If yes, which ones?
Reactivity, and under what conditions?	
Hazardous Decomposition Products	

Effects of Acute Exposure	
None	
Effects of Chronic Exposure	
None	
Irritancy of Product	
None	
Skin Sensitization	Respiratory Sensitization
None	None
Carcinogenicity — IARC	Carcinogenicity — ACGIH
None	None
Reproductive Toxicity	Teratogenicity
None	None
Embryotoxicity	Mutagenicity
None	None
Name of Synergistic Products/Effects	
None	

SECTION 12 — ECOLOGICAL INFORMATION

[Aquatic Toxicity]



No data available for this product.

SECTION 13 — DISPOSAL CONSIDERATIONS

Waste Disposal

Dispose of water according to normal refuse requirements.

SECTION 14 — TRANSPORT INFORMATION

Special Shipping Information

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 product is safe for air/ocean transportation and not regulated by IATA DGR/IMDG.

PIN

TDG
Not regulated.[DOT]
Not regulated.[IMO]
Not regulated.[ICAO]
Not regulated.**SECTION 15 — REGULATORY INFORMATION**

[WHMIS Classification]



[OSHA]

This product does not contain any hazardous ingredients above trigger levels.

[SERA]

[TSCA]

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by CPR.

SECTION 16 — OTHER INFORMATION

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it shall make their own determination of the effects, properties, and protections which pertain to their particular conditions.

The above information indicates that all the components compliance with the EU safety regulations Regulation (EC) No 1272/2008 (CLP) and Regulation (EC) No 1907/2006 (REACH)