Material Safety Data Sheet

MSDS –R0180C Rev A

Section 1-Product and Company Information

Product Name: ***OnSite*** COVID-19 IgG/IgM Rapid Test
Product Description: The OnSite COVID-19 IgG/IgM Rapid Test is a lateral flow immunoassay for the detection of anti-SARS-CoV-2 IgG and IgM antibodies in human serum, plasma or whole blood. It is intended to be used by healthcare professionals as an aid in the diagnosis of infection with SARS-CoV-2 coronavirus.

Product Catalog: R0180C

Company: CTK Biotech, Inc
Street Address: 13855 Stowe Dr.
City, State, Zip, Country: Poway, CA 92064, USA
Technical Phone: 858-457-8698 **Emergency Phone:** 858-344-2199
Fax: 858-535-1739
Website: www.ctkbiotech.com

Section 2- Hazards Identification

2.1 Classification of Substance:

Substance Name	Amount	CAS#	EC Number	R-phrases	S-phrases	UN	Hazard Class
Sodium Azide	0.09%	26628-22-8	247-852-1	R28, R32	S24-35-37	1687	6.1

According to European Directive 91/155/EEC and regulations (EC) 1272/2008 (CLP)
Sodium Azide: Not hazardous when concentration < 0.1%.

Sodium azide [NaN3], CAS# 26628-22-8 and EC No 247-852-1

GHS \ 2008/1272/EC Classification (pure form): Acute Tox. 2 *Aquatic Acute 1 Aquatic Chronic 1

Pictogram

Label(s):
Signal Word: **WARNING**

Label Hazard Statement:	**H300**: Fatal if swallowed **H400**: Very toxic to aquatic life **H410**: Very toxic to aquatic life with long-lasting effects **EUH032**: Contact with acids liberates very toxic gas
Supplemental Hazard Statement:	*None Specified*.
Precautionary Statement – Prevention:	**P264**: Wash thoroughly after handling. **P270**: Do not eat, drink or smoke when using this product. **P273**: *Avoid release to the environment.*
Precautionary Statement – Response:	**P330**: Rinse mouth. **P301** + **P312**: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
Precautionary Statement – Storage:	*None Specified*
Precautionary Statement – Disposal:	**P501**: Dispose of contents and container in accordance to local, regional, national and/or international regulations. This material and its container must be disposed of in a safe way.

2.2 Label Elements:

The product does not contain a hazardous ingredient in an amount that requires identification and labelling according to the concentration limit/cut-off values of EC directives. This product contains no hazardous constituents, or the concentration of all chemical constituents is below the regulatory threshold limits described by Occupational Safety Health Administration Hazard Communication Standard 29 CFR 1910.1200 and the European Directive 91/155/EEC, 93/112/EC and (EC) 1272/2008 (CLP).

Bio-hazards: All the biological substances are derived from in vitro culture system or animal materials which are free of known-pathogens for human. Thus, no bio-hazardous can be claimed in the product.

Section 3- Composition/Information on Ingredients

Composition

	One strip packed in a plastic cassette
1. Individually sealed pouch	0.5 g silica gel desiccant
	One plastic dropper
2. Sample Diluent	20 mM Phosphate buffer, pH 7.2-7.4
	0.09% sodium azide

Note: The strip is composed of nitrocellulose membrane, vinyl matte adhesive, fiber absorbent pad, fiber sample pad, fiber conjugate pad. The nitrocellulose membrane and the fiber conjugate pad contain dried biological substances preserved by sodium azide. The identity of each biological substance is confidential.

Section 4- First Aid Measures

Inhalation: Inhalation of any component in this kit is unlikely. If a component of this kit is inhaled and causes discomfort, move exposed individual to fresh air. Seek medical attention if breathing is difficult or symptoms persist.

Ingestion: Ingestion of small amounts of the Sample Diluent should not be toxic, however, a physician should be immediately. The animal proteins and dried reagents absorbed into the nitrocellulose membrane and the fiber conjugate pad are very unlikely to be ingested or be hazardous by ingestion. However, a physician should be consulted should ingestion occur.

Skin Contact: The Sample Diluent is not likely to be hazardous by skin contact. However, in case of contact, immediately clean skin with plenty of water. Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. The animal proteins and dried reagents absorbed into the nitrocellulose membrane and the fiber conjugate pad are very unlikely to be hazardous by skin contact, but clean the skin after use is advisable.

Eye Contact: The test device is very unlikely to be contacted by eye, however, contact physician should a contact occur. In case of contact with the Sample Diluent, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention.

Aggravating Condition: Repeated or prolonged exposure is not known to aggravate medical condition.

Section 5- Firefighting measures

5.1 Extinguishing Media: For small fires, use dry chemical, carbon dioxide, or alcohol-resistant foam. No direct contact with water.

5.2 Special Fire Fighting Procedures: This material will not significantly contribute to the intensity of a fire. Use extinguishing material suitable to the surrounding fire. Utilize proper personal protective equipment when responding to any fire. Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Move containers from fire area if it can be done without risk to personnel. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

5.3 Unusual Fire and Explosion Hazards: When involved in a fire, this material can decompose and produce irritating fumes and toxic gases (e.g., Carbon monoxide, Carbon dioxide, sulfuric dioxide).

Explosion Sensitivity to Mechanical Impact: Not sensitive under normal conditions.

Explosion Sensitivity to Static Discharge: Not sensitive under normal conditions.

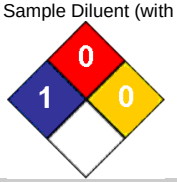
5.4 Additional Considerations

5.4.1 Flash Point	Non Combustible
5.4.2 Auto-ignition Temperature	Not Applicable

5.4.3 Upper / Lower Explosion Limit Not Applicable

5.5 NFPA 704 Ratings

Sample Diluent (with 0.09% Sodium azide)



Section 6- Accidental Release Measures

Personal Precaution: Lab coat and gloves.

Small Spill and Leak: Use absorbent paper towel or cloth to absorb the spill solution and dispose or clean the contaminated surface in accordance with U.S. Federal, State, or local procedures or appropriate standards

Large Spill and Leak: Not applicable.

Section 7- Handling and Storage

Handling: Don't eat, drink, smoke or apply cosmetics in laboratory area. Use the product according to the product insert.

Storage: Keep container tightly closed. Keep product at 2-30ºC**.** Do not freeze or expose to temperature higher than 30ºC. Keep away from children.

Section 8- Exposure Control/Personal Protection

8.1 Exposure Limits:

CAS#	Chemical Name	OSHA (PEL)	ACGIH (TLV) *	MAK
26628-22-8	Sodium Azide	0.3 mg/ m^3	0.29 mg/ m^3	0.2 mg/ m^3

Biological Exposure Index (ACGIH).

Other exposure limits for potential decomposition products: None.

8.2 Occupational Exposure Controls:

Engineering Control: Eye bath. Use adequate ventilation to keep airborne concentrations low.

Hygiene Measures: Wash hands after handling compounds and before eating, smoking, using lavatory, and at the end of the day.

Personal Protective Equipment:

Respiratory Protection None needed under normal conditions of use
Skin and Body Lab coat as indicated by general lab practice guidelines.
Eyes Safety glasses or face shield are recommended to prevent eye contact.
Hand Compatible chemical resistant gloves**.**

Section 9- Physical/Chemical Properties

	Boiling Point	Melting point	Special gravity	Vapor pressure	Vapor density	Evapora-Tion rate	pH	Water solubility	Appearance and odor
Sodium azide	**N/A**	**275**	1.85	**N/A**	**2.2**	**N/A**	**N/A**	**42% at 17ºC**	**odorless**

Section 10- Stability and Reactivity

	Stability Conditions	Materials to avoid	Hazardous to avoid	Hazardous decompo-sition or Bio-products	Polymeri-zation
Sodium azide	Stable	Incompatible Materials > 250ºC.	Acids, metals, caustics, acid chlorides, peroxides and hydroperoxides, and oxidizing agents	Nitrogen oxides, nitrogen, hydrazoic acid	Not occur

Section 11- Toxicological Information

No adverse effects on the health are expected from the components of the product. There is no aquatic toxicity data for this product at this time. Individual aquatic toxicity studies have been completed for the below listed chemicals.

Sodium Azide

RTECS Number: VYB050000
Toxicity Data and References:
Orl; hmn: TDLo: 710 µg/kg — JCPAAK 28:350, 1975.
Orl; man: LDLo: 143 mg/kg — JTCTDW 24:339, 1986.
Orl; wmn: LDLo: 14 mg/kg Arrythmias — JFSCAS 35: 193, 1990.
ipr; rat: LdLo: 30mg/kg — PHRPA6 58:607, 1943.
Toxicology Review Reference FNSCA6 2:67, 1973.
Genetic Data and References:
Fbr; hmn: Dose: 50mg/L DNA inhibition STBIBN 78: 165, 1980.
Lvr; rat; Dose: 1 mmol/L Mutations in mammalian somatic cells MUREAV 77:293, 1980.
Tumorigenic Data References:
Orl; rat; Dose: 2730 mg/kg/ 78W-C Skin, appendage and endocrine system tumors. JJIND8 67:75, 1981.
Orl; rat; Dose: 5460 mg/kg/ 78W-C Skin, appendage and endocrine system tumors. JJIND8 67:75, 1981.

Refer to the Registry of Toxic Effects of Chemical Substances (RTECS) for definitions of abbreviations used in the above text and for additional information. This report contains only selected information from the RTECS.

Section 12- Ecological Information

12.1 Environmental Fate (Sodium Azide):
When released into the soil, this material is not expected to biodegrade. When released into the soil, this material is expected to leach into groundwater. When released into the air, this material may be moderately degraded by photolysis.

12.2 Environmental Toxicity (Sodium Azide):
Dangerous to the environment. Very toxic to aquatic organisms; may cause long term adverse effects in the aquatic environment. Freshwater Fish Species Data:
96 Hr LC50 Oncorhynchus mykiss: 0.8 mg/L;
96 Hr LC50 Lepomis macrochirus: 0.7 mg/L;
96 Hr LC50 Pimephales promelas: 5.46 mg/L [flow-through]

12.3 Mobility, persistence and degradation data are not available for the components of this product. There is limited potential for the components within this product to accumulate in plant or animal systems.

Section 13- Disposal Consideration

Methods of Disposal; Waste of Residues, Contaminated Packaging Waste must be disposed of in accordance with federal, state and local environmental control regulations. *This product is not considered a RCRA hazardous waste.*
Accumulation of sodium azide in the sink may form highly explosive metal azides. Don't dispose the solid product into the sink.

Section 14- Transport Information

14.1 U.S. Transportation

This product is regulated per 49 CFR 172.101, the U.S. department of transportation:

Proper Shipping Name: None
Non-Hazardous for Transport: This substance is considered to be non-hazardous for transport.

14.2 Canadian Transportation

The above-listed DOT basic description applies to this product under the regulations of Transport Canada.

14.3 International Air Transportation

This product is regulated per International Air Transportation Association (IATA) Dangerous Goods Regulations:

Proper Shipping Name: None
Non-Hazardous for Transport: This substance is considered to be non-hazardous for air transport.

Section 15- Regulatory Information

15.1 U.S. Federal and State Regulations

	Sodium Azide
40 CFR 355.30/355.40 - SECTION 302	Not applicable
40 CFR 302.4 – SECTION 304	Not applicable
40 CFR 372.65 – SECTION 313	Not applicable

U.S. SARA SECTION 311/312 FOR KIT: Acute health effects; chronic health effects.
U.S. TSCA INVENTORY STATUS: The components of this product are listed on the TSCA Inventory.
OTHER U.S. FEDERAL REGULATIONS: Not applicable.
CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): No

15.2 Label Information

ANSI 129.1 Not required for component or kit

ENVIRONMENTAL HAZARDS:

Do not discharge effluent containing this kit into streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

15.3 Canadian Regulations:

CANADIAN DSL/NDSL INVENTORY STATUS: Sodium Azide is listed on the DSL Inventory.
CANADIAN WHMIS SYMBOLS: None Required

15.4 Hazardous Material Information System (USA)

Health	1
Fire Hazard	0
Reactivity	0
Personal Protection	B

15.5 Markings According to European Community 1999/45/EC, 2001/59/EC, 2001/60/EC, 2006/102/EC Guidelines:

This product has been classified and labeled in accordance with applicable European Community (EC) Directives (refer to 1999/45/EC, 2001/59/EC and 2001/60/EC).

Hazard Determining Substance(s) of Labeling: (rated under 1999/45/EC unless otherwise specified): 0.09% Sodium azide, EC No 247-852-1 and CAS# 26628-22-8 [Harmful:Xn; R 28 R32; S 24-35-37].

Section 16- Other Information

Risk Phrases:
R 28 Very toxic if swallowed
R 32 Contact with acids liberates very toxic gas

Safety Phrases:
S 24 Avoid contact with skin.
S 35 This material and its container must be disposed of in a safe way.
S 37 Wear suitable protective gloves.

Notice to Reader

The contained information in this MSDS are in accordance with Annex II of Regulation no.1907/2006 (REACH) and in accordance with ANSI “Standard for Hazardous Industrial Chemicals - Material Safety Data Sheets – Preparation” (ANSI Z400.1-2004) as recommended by US OSHA.

To the best of our knowledge, this information contained herein is accurate. However, neither the above named supplier nor may of its subsidiaries assume any liability whatsoever for the accuracy or completeness pf the information contained herein.
Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that these are the only hazards that exist.