

Safety Data Sheet

(SDS)

Creation Date:2020/09/22

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Prepared according to UN GHS (the 8th revised edition)

Product Name:SARS-CoV-2 antigen Test Kit(LFIA)

Model:20 pcs/box

Company Name:Jiangsu Medomics Medical Technology Co., Ltd.



Written by : Jiangsu Medomics Medical Technology Co., Ltd.



1、 Identification of the chemical and supplier

1.1 Product identifier

Product Name:SARS-CoV-2 antigen Test Kit(LFIA)

Product Model:20 pcs/box

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses:To qualitatively detect SARS-CoV-2 in human samples in vitro.

Uses advised against:Please consult manufacturer.

1.3 Details of the supplier of the Safety Data Sheet

Name of the company:Jiangsu Medomics Medical Technology Co., Ltd.

Address of the company:F3, Building D, Sino-Danish Ecological Life Science Industrial Park, No. 3-1 Xinjinhu Road, Jiangbei New District, Nanjing, Jiangsu province, CHINA

Telephone number:+86 (0) 25-58601060

Fax number:/

Zip code:/

Email address:/

1.4 Emergency phone number:+86 (0) 25-58601060

2、 Hazards identification

2.1 Hazard classification according to GHS:

The product is not dangerous and it has no hazardous classification.

2.2 Label elements

Hazard pictograms:None.

Signal word:None.

2.3 Hazard statements:

None.

2.4 Precautionary statements

2.4.1 Prevention

None.

2.4.2 Response

None.

2.4.3 Storage

None.

2.4.4 Disposal

None.

2.5 Hazard description

2.5.1 Physical and chemical hazards

This product is normally used without hazard.

2.5.2 Health hazards

None.

2.5.3 Environmental hazards

Please refer to 12th chapter of SDS.



3、 Composition/information on ingredient

Substance	Preparation		
Component	CAS No.	Concentration (weight%)	
Test cassettes	—	55	
Lysis buffer	—	15	
Sampling tubes	—	8	
droppers	—	4	
Instructions	—	2	
sterile swabs	—	16	

4、 First aid measures

4.1 Description of first aid measures

General advice: Immediate medical attention is required. Show this safety data sheet (SDS) to the doctor in attendance.

Skin contact: Wash off with plenty of water, take off contaminated clothing and shoes immediately.

Eye contact: Wash with running water or saline, Seek medical attention if necessary.

Inhalation: Move to fresh air, Keep the airway open, Seek medical attention if you feel unwell.

Intake: Clean up the mouth, induce vomiting, seek medical attention.

Protecting of first-aiders: Ensure that medical personnel are aware of the substance involved. Take precautions to protect themselves and prevent spread of contamination.

4.2 Indication of any immediate medical attention and special treatment needed

- 1、 Treat symptomatically.
- 2、 Symptoms may be delayed.

5、 Firefighting measures

5.1 Extinguishing media

- 1、 **Suitable extinguishing media:** Water, alcohol-resistant foam, dry powder, carbon dioxide.
- 2、 **Unsuitable extinguishing media:** No data available

5.2 Specific hazards arising from the substance or mixture

- 1、 No data available.

5.3 Advice for firefighters

- 1、 As in any fire, wear self-contained breathing apparatus (MSHA/NIOSH approved or equivalent) and full protective gear.
- 2、 Fight fire from a safe distance, with adequate cover.
- 3、 Prevent fire extinguishing water from contaminating surface water or the ground water system.

6、 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- 1、 Emergency personnel wear positive pressure self-contained breathing apparatus. Wear protective and anti-static clothing. Wear chemical impermeable gloves.
- 2、 Ensure adequate ventilation. Remove all sources of ignition.
- 3、 Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.
- 4、 Use personal protective equipment. Avoid breathing vapours, mist, gas or dust.

6.2 Environmental precautions

- 1、 Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up

- 1、 Adhered or collected material should be promptly disposed of, in accordance with appropriate laws

and regulations.

- Remove all sources of ignition. Use spark-proof tools and explosion-proof equipment.

7、 Handling and storage

7.1 Precautions for handling

- Closed operation, full ventilation.
- Operators must be specially trained to strictly abide by the operating procedures.
- It is recommended that operators wear self-priming filter dust masks and chemical safety glasses.
- Keep away from fire, heat, and smoking in the workplace.
- Use explosion-proof ventilation systems and equipment.

7.2 Precautions for storage

- Store in a cool, ventilated warehouse.
- Keep away from fire and heat.
- It should be stored separately from oxidants, reducing agents, halogens, etc., and should not be mixed.

8、 Exposure controls/personal protection

8.1 Control Parameters

8.1.1 Occupational exposure limits

Occupational Exposure limit values

Component	Country/Region	Limit value - Eight hours		Limit value - Short term	
		ppm	mg/m ³	ppm	mg/m ³
All components	USA - OSHA	Unspecified	Unspecified	Unspecified	Unspecified
	South Korea	Unspecified	Unspecified	Unspecified	Unspecified
	Ireland	Unspecified	Unspecified	Unspecified	Unspecified
	Germany(AGS)	Unspecified	Unspecified	Unspecified	Unspecified
	Denmark	Unspecified	Unspecified	Unspecified	Unspecified
	Australia	Unspecified	Unspecified	Unspecified	Unspecified

8.1.2 Biological limit values

Biological limit values: No information available

8.1.3 Monitoring methods

1、 EN 14042 Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.

2、 BZ/T 160.1~GBZ/T 160.81-2004 Determination of toxic substances in workplace air (Series standard) .

8.2 Engineering controls

- Ensure adequate ventilation, especially in confined areas.
- Ensure that eyewash stations and safety showers are close to the workstation location.
- Use explosion-proof electrical/ventilating/lighting/equipment.
- Set up emergency exit and necessary risk-elimination area.

8.3 Personal protection equipment

General requirement:



Eye protection: Tightly fitting safety goggles (approved by EN 166(EU) or NIOSH (US)).

Hand protection: Wear protective gloves (such as butyl rubber), passing the tests according to EN 374(EU), US F739 or AS/NZS 2161.1 standard.

Respiratory protection: Wear ordinary protective masks.

Skin and body protection: Wear ordinary protective clothing.

Other protection: Smoking, eating and drinking are forbidden on the job site. Maintain good hygiene habits.

9、 Physical and chemical properties

Appearance: White and blue paper box (containing colorless liquid tubes and plastic testing board).

Odor: Weak odor.

Odor threshold: No data available.

PH value: No data available.

Melting point/freezing point (°C): No data available.

Initial boiling point and boiling range (°C): No data available.

Flash point (closed cup, °C): No data available.

Evaporation rate: No data available.

Flammability (solid or gas): Non-flammable.

Explosion upper/lower limit [% (v/v)]: No data available.

Vapor pressure (Pa): No data available.

Vapor density (air = 1): No data available.

Relative density (water = 1): No data available.

Solubility (mg/L): No data available.

Octanol/water partition coefficient: No data available.

Auto-ignition temperature (°C): No data available.

Decomposition temperature (°C): No data available.

Viscosity: No data available.

Others: Resistance value: No data available.



10、 Stability and Reactivity

Reactivity: Contact with incompatible materials can cause decomposition or other chemical reactions.

Chemical stability: Stable under the correct conditions of use and storage.

Possibility of hazardous reactions: No data available.

Conditions to avoid: Electrostatic discharge, heat, humidity, etc.

Incompatible materials: Strong oxides, strong acids, strong bases.

Hazardous decomposition products: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11、 Toxicological information

11.1 Acute toxicity

Component	LD ₅₀ (oral)	LD ₅₀ (Transcutaneous)	LC ₅₀ (inhalation, 4h)
All components	Not available	Not available	Not available

11.2 Carcinogenicity

Component	IARC	NTP
All components	Not Listed	Not Listed

11.3 Others

Component	Corrosive skin/irritation	Serious eye damage/irritation	Skin sensitization	Respiratory sensitization	Reproductive toxicity	Specific target organ toxicity - single exposure	Specific target organ toxicity - repeated exposure	Aspiration hazard	Germ cell mutagenicity	Reproductive toxicity
All components	Not available	Not available	Not available	Not available	Not available	Not available	Not available	Not available	Not available	Not available

12、 Ecological information

12.1 Acute aquatic toxicity

Component	Fish	Crustaceans	Algae
All components	Not available	Not available	Not available

12.2 Chronic aquatic toxicity

Component	Fish	Crustaceans	Algae
All components	Not available	Not available	Not available

12.3 Others

Component	Persistence and degradability	Bioaccumulation or bioaccumulation	Soil mobility	Evaluation of PBT and vPvB results
All components	Not available	Not available	Not available	Not available

13、 Disposal considerations

Disposal considerations: Recycle as much as possible.

Waste chemicals: Contaminated packaging: Residual hazards may still exist after the contents of the packaging are emptied. Keep away from heat and sources of ignition. If possible, recycle them to the supplier for recycling.

Disposal considerations: Refer to the "Disposal" section.

14、 Transportation information

Suggestion according to IATA DGR, the substance is not subject to IATA DGR.

United Nations Dangerous Goods Number (UN No.): The product is not dangerous.

UN proper shipping name: None

UN Risk Classification: None

Packing Category: None

Packaging label: None

Marine Pollutants (Yes/No): No

Packing method: Pack according to the manufacturer's recommendations.

Transportation Note: No data available.

15、Regulatory information

International chemical inventory

Component	EINECS	TSCA	DSL	IECSC	NZIoC	PICCS	KECL	AICS
All components	N.A	N.A	N.A	N.A	N.A	N.A	N.A	N.A

【EINECS】 European Inventory of Existing Commercial Chemical Substances

【TSCA】 United States Toxic Substances Control Act Inventory

【DSL】 Canadian Domestic Substances List

【IECSC】 China Inventory of Existing Chemical Substances

【NZIoC】 New Zealand Inventory of Chemicals

【PICCS】 Philippines Inventory of Chemicals and Chemical Substances

【KECL】 Korea Existing Chemical List

【AICS】 Australia Inventory of Chemical Substances

16、Others

16.1 Reference:

【1】 IPCS:The International Chemical Safety Cards (ICSC),website:<http://www.ilo.org>

【2】 IARC,website:<http://www.iarc.fr>

【3】 OECD:The Global Portal to Information on Chemical Substances,website:<http://www.chemportal.org>

【4】 CAMEO Chemicals,website:<http://cameochemicals.noaa.gov>

【5】 NLM:ChemIDplus,website:<http://chem.sis.nlm.nih.gov>

【6】 EPA:Integrated Risk Information System,website:<http://cfpub.epa.gov>

【7】 U.S. Department of Transportation:ERG,website:<http://www.phmsa.dot.gov>

【8】 Germany GESTIS-database on hazard substance,website:<http://gestis-en.itrust.de>

16.2 Others:

1、Abbreviations and acronyms

CAS-Chemical Abstracts Service

PC-STEL- Short term exposure limit

DNEL-Derived No Effect Level

RPE-Respiratory Protective Equipment

LC50-Lethal Concentration 50%

NOEC-No Observed Effect Concentration

PBT-Persistent, Bioaccumulative, Toxic

BCF-Bioconcentration factor (BCF)

IMDG-International Maritime Dangerous Goods

UN-The United Nations

NFPA-National Fire Protection Association

CMR-Carcinogens, mutagens or substances toxic to reproduction

PC-TWA -Time Weighted Average

IARC-International Agency for Research on Cancer

PNEC-Predicted No Effect Concentration

LD50-Lethal Dose 50%

EC50-Effective Concentration 50%

POW-Partition coefficient Octanol:Water

vPvB-very Persistent,very Bioaccumulative



ICAO/IATA-International Civil Aviation Organization/International Air Transportation Association
ACGIH-American Conference of Governmental Industrial Hygienists
OECD-Organization for Economic Co-operation and Development

2、Disclaimer

This Safety Data Sheet (SDS) was prepared according to UN GHS (the 8th revised edition). The data included was derived from international authoritative database and provided by the enterprise. Other information was based on the present state of our knowledge. We try to ensure the correctness of all information. However, due to the diversity of information sources and the limitations of our knowledge, this document is only for user's reference. Users should make their independent judgment of suitability of this information for their particular purposes. We do not assume responsibility for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product.

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SDS Creation Date: 2020/09/22 (Valid in the year)

