SAFETY DATA SHEET

SECTION 1: INDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/ UNDERTAKING

1.1 Product identifier

Product name: SARS-CoV-2 Antigen Rapid Test

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

Relevant identified uses:

The SARS-CoV-2 Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swab specimens. The SARS-CoV-2 Antigen Rapid Test is for professional in vitro diagnostics use only.

Uses advised against:

None.

1.3 Details of the supplier of the safety data sheet

Manufacturer:

Name: ACON Biotech (Hangzhou) Co., Ltd.

Address: No.210 Zhenzhong Road,
West Lake District, Hangzhou,
P.R. China, 310030

Phone: +86 571 87 96 35 69

E-mail: info@aconlabs.com

Authorized Representative in the EU:

Name: MedNet GmbH

Address: Borkstrasse 10
48163 Muenster, Germany

Phone: +49 251 32266-0

1.4 Emergency telephone number: +49 030/19240

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of substance or mixture

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

2.2 Label elements

The product does not need to be labelled according to Regulation (EC) No. 1272/2008.

2.3 Other Hazards

The product does not contain any substance that meet the criteria for PBT/vPvB according to Annex XIII of Regulation (EC) No. 1907/2006.

SECTION 3: COMPOSITION /INFORMATION ON INGREDIENTS

3.1 Substance

Not Applicable.

3.2 Mixtures

3.2.1 Hazardous ingredients in Test Cassette

As per the Regulation (EC) No 1907/2006, the cassette is defined as an "Article" for which an SDS is not legally required. Thus, no substance need to be listed in this Section.

3.2.2 Hazardous ingredients in Buffer:

Extraction Buffer solution is accompanied with the SARS-CoV-2 Antigen Rapid Test in the kit box. Then concentration of the hazardous ingredients in the buffer is shown in below table:

Components	CAS number	Concentration	Classification according to Regulation (EC) No. 1278/2008 (CLP)	Specific Concentration. Limits, M-factors
Sodium azide	26628-22-8	0.02%	Acute Tox. 2 * (H300) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	N/A

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

If INHALATION: Move to fresh air. If not breathing, give artificial respiration. Do not use mouth-to-mouth method if victim ingested or inhaled; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required.

If SKIN Contact: Take off immediately all contaminated clothing. Wash off immediately with plenty of water for at least 15 minutes. Immediate medical attention is required.

If EYE Contact: Immediately flush eyes with plenty of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Get medical attention immediately.

If INGESTION: Clean mouth with water. Do not induce vomiting. Risk of aspiration! Keep airways free. Pulmonary failure possible after aspiration of vomit. Call a physician or Poison Control Center immediately.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact: May cause skin irritation, corrosion and dermatitis. Drying-out effect resulting in rough and chapped skin.

Symptoms/effects after eye contact: May cause eye damage and corneal clouding.

Symptoms/effects after ingestion: May cause vomit.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Use water spray, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

No data available.

5.3 Advice for firefighters

Wear protective eyewear, gloves and clothing. Ensure self-safety.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Not applicable.

6.2 Environmental precautions

Dispose the tests as medical rubbish.

6.3 Methods and material for containment and cleaning up

Dispose the tests as medical rubbish.

6.4 Reference to other sections

None.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Wear suitable laboratory coat and gloves. Avoid contacting with skin, eyes and mucous membranes. Take care not to splash, spill or splatter the buffer. Do not eat, drink or smoke in laboratory areas. Do not pipette the buffer by mouth. Wash hands and remove contaminated clothing after use.

7.2 Conditions for safe storage, including any incompatibilities

Store in the sealed package either at room temperature or refrigerated (2-30℃) and keep out of direct sunlight to ensure the product quality.

7.3 Specific end use(s)

No specific uses.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limit Values:

Substance:	**Sodium azide**				
CAS No.	**26628-22-8**				
Country	**Limit Value-Eight hours**		**Limit Value-Short term**		**Legal basis**
	ppm	**mg/m^3**	**ppm**	**mg/m^3**	
Belgium		0.1		0.3	Data from GESTIS

Denmark		0.1		0.2	Database
European Union		**0.1**		**0.3 (1)**	
Finland		0.1		0.3 (1)	
France		**0.1**		**0.3**	
Germany (AGS)		0.2		0.4 (1)	
Germany (DFG)		0.2 inhalable aerosol		0.4 inhalable aerosol	
Hungary		0.1		0.3	
Ireland		0.1		0.3 (1)	
Italy		0.1		0.3	
Latvia		0.1		0.3 (1)	
Poland		0.1		0.3	
Spain		0.1		0.3	
Sweden				0.29 (1)	
Switzerland		0.2 inhalable aerosol		0.4 inhalable aerosol	
The Netherlands		0.1		0.3	
Turkey		0.1		0.3 (1)	
United Kingdom		0.1		0.3	

	Remarks
European Union	Bold-type: Indicative Occupational Exposure Limit Values and Limit Values for Occupational Exposure Binding Occupational Exposure Limit Value - BOELV ~ (1) 15 minutes average value
Finland	(1) 15 minutes average value
France	Bold type: Restrictive statutory limit values
Germany (AGS)	(1) 15 minutes average value
Germany (DFG)	STV 15 minutes average value
Ireland	(1) 15 minutes reference period
Italy	skin
Latvia	(1) 15 minutes average value
Spain	Skin
Sweden	(1) Ceiling Limit value
Turkey	(1) 15 minutes average value

8.1.2 Biological Limit Values:

No data available.

8.1.3 Monitoring Methods:

No data available.

8.2 Exposure controls

8.2.1 Appropriate engineering controls:

Use with adequate ventilation.

8.2.2 Personal protective equipment:

Use with adequate ventilation.

Eye/face protection: Not applicable.

Skin protection:

Hand protection: Not applicable.

Body protection: Not applicable.

Respiratory protection: Not applicable.

Thermal hazards: Not applicable.

8.2.3 Environmental exposure controls:

Do not allow to enter into surface water or drains.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

The below data applies to the buffer solution:

Appearance	colorless Liquid
Odor	odorless
Odor threshold	No data available
pH	8.0
Melting point/freezing point	No data available
Initial boiling point and boiling range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Upper/lower flammability or explosive limits	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Solubility (ies)	No data available
Partition coefficient: n-octanol/water	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Oxidising properties	No data available

9.2 Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Sodium azide (CAS No. 26628-22-8)	
Reaction	No data available.

10.2 Chemical stability

No known instability under normal conditions of use or storage.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

Keep away from open flames, hot surfaces and sources of ignition. Avoid dust formation.

10.5 Incompatible material

Acids, Oxidizing agents, Peroxides, Acid chlorides, Metals.

10.6 Hazardous decomposition products

Nitrogen oxides (NOx), Sodium oxides, Carbon monoxide (CO), Carbon dioxide (CO2).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Sodium azide (CAS No. 26628-22-8)	
LD_{50} Oral (Mouse)	27 mg/kg
LC_{50} Inhalation (Rats)	0.054 and 0.52 mg/L
LD_{50} Dermal (Rabbits)	500-1000mg/kg

Skin corrosion/irritation No data available.

Serious eye damage/irritation No data available.

Respiratory or skin sensitization No data available.

Germ cell mutagenicity No data available.

Carcinogenicity No component in this product is confirmed carcinogenicity by ACGIH, IARC, NTP or OSHA.

Reproductive toxicity Sodium azide has a drastically toxic effect on the in vitro growth of mouse embryos at concentrations of 10^{-4} mol/L in the petri dish or greater.

STOT-single exposure No data available.

STOT-repeated exposure No data available.

Aspiration hazard No data available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Sodium azide (CAS No. 26628-22-8)	
LC_{50} (Fish 1)	0.7 mg/L (96h, Lepomis macrochirus)
LC_{50} (Fish 2)	5.46 mg/L (96h, flow-through (Pimephales promelas)
LC_{50} (Fish 3)	0.8 mg/L (96h, Oncorhynchus mykiss)

12.2 Persistence and degradability

Sodium azide (CAS No. 26628-22-8)	
Persistence and degradability	Soluble in water Persistence is unlikely based on information available.

12.3 Bioaccumulative potential

Sodium azide (CAS No. 26628-22-8)	
Bioaccumulative potential	No data available.

12.4 Mobility in soil

Sodium azide (CAS No. 26628-22-8)	
Mobility in soil	Will likely be mobile in the environment due to its water solubility.

12.5 Results of PBT and vPvB assessment

This product does not contain any substances that are assessed to be PBT or vPvB.

12.6 Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Dispose as medical rubbish after being used

Contaminated packaging

Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number

This product is not regulated for transport.

14.2 UN proper shipping name

This product is not regulated for transport.

14.3 Transport hazard class (es)

This product is not regulated for transport.

14.4 Packing group

This product is not regulated for transport.

14.5 Environmental hazards

No data available.

14.6 Special precautions for user

No data available.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

No data available.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Not data available.

15.2 Chemical safety assessment

No data available.

SECTION 16: OTHER INFORMATION

16.1 Indication of Changes:

Version 1 Revision 0: First version, document in accordance with requirements for safety data sheets introduced by Regulation (EC) No 1907/2006 (REACH).

16.2 Abbreviations and acronyms:

Acute Tox. 2: Acute Toxicity, Category 2

Aquatic Acute 1: Hazard to the aquatic environment – Acute, category 1

Aquatic Chronic 1: Hazard to the aquatic environment – Chronic, category 1

PBT: Persistent, Bioaccumulative and Toxic;

vPvB: Very Persistent and Very Bioaccumulative

16.3 Classification and procedure used to derive the classification for mixtures according to Regulation (EC) No 1272/2008 (CLP):

The product is not classified as a hazard mixture as per Regulation (EC) No 1272/2008 (CLP).

16.4 Relevant H-statements (number and full text):

H300 Fatal if swallowed.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

16.5 Further information

This information is based upon the present state of our knowledge.

This SDS has been compiled and is solely intended for this product.