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## SAFETY DATA SHEET

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

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#### 1.1 Product identifier

**Product name:** SARS-CoV-2 Antigen Rapid Test (Self-Testing)

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

**Relevant identified uses:**

The SARS-CoV-2 Antigen Rapid Test (Self-Testing) is a rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swab specimens.

For in vitro diagnostic use only. For self-testing use.

**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

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### SECTION 2: HAZARDS IDENTIFICATION

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#### 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.

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## SECTION 3: COMPOSITION /INFORMATION ON INGREDIENTS

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### 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 are 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
Triton X-100	9002-93-1	1%	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	N/A

Note: Triton X-100 is a substance included in the candidate list of substances of very high concern (SVHC) for authorisation and the sunset date is 4 January 2021 according to Regulation (EC) No. 1907/2006 (REACH). However, as the COVID-19 pandemic, the sunset date for Triton X-100 was postponed until 22 December 2023 with regard to the uses for the research, development and production of medicinal products, medical devices, or accessories to medical devices, including in vitro diagnostic medical devices, for the diagnosis, treatment or prevention of COVID-19 and use in such medical devices or accessories according to Commission Regulation (EU) 2020/2160.

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## SECTION 4: FIRST AID MEASURES

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### 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

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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.

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### **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.

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### **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. Do not allow to enter into surface water, drains or sanitary sewer system. Discharge into the environment must be avoided.

#### **6.3 Methods and material for containment and cleaning up**

Soak up the buffer with insert absorbent material. Keep in suitable, closed containers for disposal. Dispose the tests as medical rubbish.

#### **6.4 Reference to other sections**

See Section 13 DISPOSAL CONSIDERATIONS for details.

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### **SECTION 7: HANDLING AND STORAGE**

#### **7.1 Precautions for safe handling**

Avoid contacting with skin, eyes and mucous membranes. Take care not to splash, spill or splatter the buffer. Do not eat, drink or smoke before and during the test. Do not pipette the buffer by mouth. Wash hands and remove contaminated clothing after use. Avoid ingestion and inhalation.

#### **7.2 Conditions for safe storage, including any incompatibilities**

Store in the sealed package either at room temperature or refrigerated (2-30°C) 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 <sup>3</sup>	ppm	mg/m <sup>3</sup>	
Belgium		0.1		0.3	Data from GESTIS Database
Denmark		0.1		0.2	
European Union		<b>0.1</b>		<b>0.3 (1)</b>	
Finland		0.1		0.3 (1)	
France		<b>0.1</b>		<b>0.3</b>	
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:

<b>Appearance</b>	colorless Liquid
<b>Odor</b>	odorless
<b>Odor threshold</b>	No data available
<b>pH</b>	8.0~9.0
<b>Melting point/freezing point</b>	No data available
<b>Initial boiling point and boiling range</b>	No data available
<b>Flash point</b>	No data available
<b>Evaporation rate</b>	No data available
<b>Flammability (solid, gas)</b>	No data available

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<b>Upper/lower flammability or explosive limits</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Relative density</b>	No data available
<b>Solubility (ies)</b>	No data available
<b>Partition coefficient: n-octanol/water</b>	No data available
<b>Auto-ignition temperature</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Viscosity</b>	No data available
<b>Explosive properties</b>	No data available
<b>Oxidising properties</b>	No data available

## 9.2 Other information

No data available.

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## SECTION 10: STABILITY AND REACTIVITY

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### 10.1 Reactivity

Sodium azide (CAS No. 26628-22-8)	
Reaction	No data available.
Triton X-100 (CAS No. 9002-93-1)	
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 (NO<sub>x</sub>), Sodium oxides, Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>).

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## SECTION 11: TOXICOLOGICAL INFORMATION

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### 11.1 Information on toxicological effects

#### Acute toxicity

Sodium azide (CAS No. 26628-22-8)	
LD <sub>50</sub> Oral (Mouse)	27 mg/kg
LC <sub>50</sub> Inhalation (Rats)	0.054 and 0.52 mg/L
LD <sub>50</sub> Dermal (Rabbits)	500-1000mg/kg

<b>Triton X-100 (CAS No. 9002-93-1)</b>	
LD <sub>50</sub> Dermal (Rabbits)	8.000 mg/kg
<b>Skin corrosion/irritation</b>	No data available.
<b>Serious eye damage/irritation</b>	No data available.
<b>Respiratory or skin sensitization</b>	No data available.
<b>Germ cell mutagenicity</b>	No data available.
<b>Carcinogenicity</b>	No component in this product is confirmed carcinogenicity by ACGIH, IARC, NTP or OSHA.
<b>Reproductive toxicity</b>	Sodium azide has a drastically toxic effect on the in vitro growth of mouse embryos at concentrations of 10 <sup>-4</sup> mol/L in the petri dish or greater.
<b>STOT-single exposure</b>	No data available.
<b>STOT-repeated exposure</b>	No data available.
<b>Aspiration hazard</b>	No data available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

<b>Sodium azide (CAS No. 26628-22-8)</b>	
LC <sub>50</sub> (Fish 1)	0.7 mg/L (96h, Lepomis macrochirus)
LC <sub>50</sub> (Fish 2)	5.46 mg/L (96h, flow-through (Pimephales promelas)
LC <sub>50</sub> (Fish 3)	0.8 mg/L (96h, Oncorhynchus mykiss)
<b>Triton X-100 (CAS No. 9002-93-1)</b>	
LC <sub>50</sub> (Fish 1)	4 – 8.9 mg/l (96 h, Pimephales promelas)

### 12.2 Persistence and degradability

<b>Sodium azide (CAS No. 26628-22-8)</b>	
Persistence and degradability	Soluble in water Persistence is unlikely based on information available.
<b>Triton X-100 (CAS No. 9002-93-1)</b>	
Persistence and degradability	No data available

### 12.3 Bioaccumulative potential

<b>Sodium azide (CAS No. 26628-22-8)</b>	
Bioaccumulative potential	No data available.
<b>Triton X-100 (CAS No. 9002-93-1)</b>	
Bioaccumulative potential	No data available.

### 12.4 Mobility in soil

<b>Sodium azide (CAS No. 26628-22-8)</b>	
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Mobility in soil	Will likely be mobile in the environment due to its water solubility.
<b>Triton X-100 (CAS No. 9002-93-1)</b>	
Mobility in soil	No data available.

### 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

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## SECTION 13: DISPOSAL CONSIDERATIONS

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### 13.1 Waste treatment methods

#### Product

Dispose as medical rubbish after being used and should be in accordance with local, state or national legislation. Do not allow to enter into surface water, drains or sanitary sewer system.

#### 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.

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## SECTION 14: TRANSPORT INFORMATION

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### 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.

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## SECTION 15: REGULATORY INFORMATION

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### 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.



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## SECTION 16: OTHER INFORMATION

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### 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).

Version 2 Revision 0: Update the hazardous ingredients in Section 3.2.2 to add the Triton X-100. Also, the information in Section 10, Section 11, Section 12, Section 16.2 and 16.3 were updated accordingly.

Version 3 Revision 0: Update the hazardous ingredients in Section 3.2.2 to add the note for the Triton X-100 used in the SARS-CoV-2 Antigen Rapid Test (Self-Testing) according to Commission Regulation (EU) 2020/2160.

### 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

Acute Tox. 4: Acute Toxicity, Category 4

Skin Irrit. 2: Skin Irritation, Category 2

Eye Irrit. 2: Eye Irritation, Category 2

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.

H302 Harmful if swallowed.

H315 Cause skin irritation.

H319 Cause serious eye irritation.

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.