

1.3

# SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), Annex II; amended by Regulation (EU) 2020/878.

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

1.1 Product identifier

Trade Name ACCURUN® Swab Reference Materials:

ACCURUN® Swab SARS-CoV-2 Reference Material ACCURUN® Swab Flu A/B Reference Material ACCURUN® Swab RSV Reference Material

In vitro diagnostic reagent. For professional use only.

Reference No. Material Number: 2020-0177

Material Number: 2020-0178 Material Number: 2020-0179

1.2 Relevant identified uses of the substance or

mixture and uses advised against

Identified Use(s)

Details of the supplier of the safety data sheet

Company Identification

LGC Clinical Diagnostics, Inc

37 Birch Street Milford, MA 01757

USA.

Telephone (508) 244-6400 US Toll Free: (800) 676-1881 E-Mail (competent person) CDx-CustomerService@LGCGroup.com

1.4 Emergency telephone number

Emergency Phone No.

For Chemical Emergency Spill, Leak, Fire, Exposure, or

Accident

Call CHEMTREC Day or Night

Within USA and Canada: 1-800-424-9300 or +1 703-527-3887 (collect calls accepted)

Account number: CCN12505

AUSTRALIA - POISONS INFORMATION CENTER

Telephone: 13 11 26

CANADIAN TRANSPORT EMERGENCY CENTER

Telephone: (1) 613 996 6666

#### **SECTION 2: HAZARDS IDENTIFICATION**

2.1 Classification of the substance or mixture

Regulation (EC) No. 1272/2008 (CLP) GHS Classification in accordance with

29 CFR 1910 (OSHA HCS)

Not classified as hazardous. Not classified as hazardous.

**2.2 Label elements** No measures required.

2.3 Other hazards Contains SARS-CoV-2, Human RSV, Influenza A, and/or

Influenza B viral strains that have been inactivated to render

them noninfectious.

### **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

3.2 Mixtures

Description: Swab containing dried chemicals and biochemicals

Dangerous components:



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Hazardous Ingredient(s)	CAS No.	EC No.	REACH Registration No.	Classification code: Hazard Statement(s)	%W/W
Sodium azide*	26628-22-8	247-852-1	Not available	Acute Tox. 2; H300 Acute Tox. 1; H310 STOT RE 2; H373 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032	< 0.1
Polyethylene glycol tert- octylphenyl ether / Igepal CA-630**	9002-93-1	618-344-0	Not available	Acute Tox. 4; H302 Eye Irrit. 2; H319 Aquatic Chronic 2; H411	< 0.1

<sup>\*</sup> Substance with a community exposure limit.

#### 3.3 **Additional Information**

For full text of H Statements see section 16.

#### **SECTION 4: FIRST AID MEASURES**



Description of first aid measures

Inhalation Supply fresh air; consult doctor in case of complaint.

Skin Contact Wash skin with soap and water.

Eye Contact Rinse cautiously with water for several minutes. Consult a

doctor in case of complaint.

Wash out mouth with water. Consult a doctor. Ingestion

4.2 Most important symptoms and effects, both

acute and delayed

None.

4.3 Indication of any immediate medical attention

and special treatment needed

None

## **SECTION 5: FIREFIGHTING MEASURES**

5.1 **Extinguishing media** 

Advice for fire-fighters

and emergency procedures

Suitable Extinguishing media CO2, powder or water spray. Fight larger fires with water

spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or

mixture

5.3

In case of fire, the following can be released: Carbon oxides

(COx), nitrogen oxides (NOx).

Use fire-extinguishing methods suitable to surrounding

conditions.

Wear full protective suit and self-contained breathing

aparatus (SCBA) when extinguishing fires.

### **SECTION 6: ACCIDENTAL RELEASE MEASURES**

6.1 Personal precautions, protective equipment Isolate spillage and clean up immediately.

Refer to Section 8 for protective measures when handling the

spillage.

6.2 **Environmental precautions** Avoid release to the environment.

6.3 Methods and material for containment and Collect material and dispose of as waste according to

Section 13.

Swab down area with Chloros or other disinfecting agent.

6.4 Reference to other sections 8. 13

Revision: 1 Page: 2/6 Date: Dec 15, 2023 ACCURUN® Swab Reference Materials

cleaning up

<sup>\*\*</sup> Candidate List of Substances of Very High Concern for Authorisation (SVHC)



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

7.1 Precautions for safe handling

This product should be handled as a potentially infectious material, as no known test method /inactivation procedure can offer complete assurance that products derived from materials of human origin will not transmit infectious agents. Refer to Directive 2000/54/EC or US regulation 29 CFR 1910.1030 for information on handling biohazardous materials.

Avoid contact with the eyes, skin and mucous membranes.

Keep out of reach of children.

Wash hands before breaks and after work.

Clean work areas with hypochlorite or other disinfecting

agent.

7.2 Conditions for safe storage, including any

incompatibilities

Store in the original container at 2 to 30°C.

7.3 Specific end use(s) In vitro diagnostic reagent. Assay controls.

#### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 **Control parameters**

#### 8.1.1 **Occupational Exposure Limits**

EU IOELV / UK EH40

SUBSTANCE.	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m³)	STEL (ppm)	STEL (mg/m³)	Note
Sodium azide	26628-22-8		0.1		0.3	Sk

Sk - Can be absorbed through skin.

8.2 **Exposure controls** 

8.2.1 Appropriate engineering controls 8.2.2

Personal protection equipment

Not relevant for this material.

Eye/ face protection Safety glasses recommended.

Hand protection Disposable gloves.



Latex / natural rubber, Nitrile rubber. Material of gloves:

Penetration time of glove material: Gloves resistance is not critical when the product is handled

according to the instructions for use.

Body protection Laboratory coat. Respiratory protection Not normally required.

8.2.3 **Environmental Exposure Controls** No special measures are required.

#### **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

#### 9.1 Information on basic physical and chemical properties

Physical state Solid

Colour Varies according to substance

Odour No odour. Melting point/freezing point Not determined. Boiling point/boiling range (°C): Not determined. Flammability Not flammable Lower and upper explosion limit Not applicable.

Flash Point (°C) Not applicable.

Revision: 1 Page: 3/6 Date: Dec 15, 2023



According to Regulation (EC) No. 1907/2006 (REACH), Annex II; amended by Regulation (EU) 2020/878.

Auto-ignition temperature Not determined. Decomposition Temperature (°C) Not determined. pΗ Not determined. Kinematic Viscosity Not applicable. Solubility (Water) Partially soluble. Partition coefficient: n-octanol/water (log value) Not determined. Density (g/ml) Not determined. Relative vapour density at 20 °C Not determined. Particle characteristics Not determined.

#### 9.2 Other information

9.2.1 Information with regard to physical hazard classes

Explosive properties Not explosive.
Oxidising properties Not oxidising

**9.2.2** Other safety characteristics No information available.

### **SECTION 10: STABILITY AND REACTIVITY**

10.1 Reactivity None known.

10.2 Chemical stability The product is stable in accordance with the recommended

storage conditions.

10.3 Possibility of hazardous reactions Hazardous polymerisation will not occur.

10.4 Conditions to avoid None.
 10.5 Incompatible materials None known.
 10.6 Hazardous decomposition products None known.

#### **SECTION 11: TOXICOLOGICAL INFORMATION**

#### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

#### 11.1.2 Mixtures

Acute toxicity Based upon the available data, the classification criteria are

not met.

Skin corrosion/irritation Based upon the available data, the classification criteria are

not met.

Serious eye damage/irritation Based upon the available data, the classification criteria are

not met.

Respiratory/skin sensitization Based upon the available data, the classification criteria are

not met.

Germ cell mutagenicity

Based upon the available data, the classification criteria are

not met.

Carcinogenicity Based upon the available data, the classification criteria are

not met.

Reproductive toxicity Based upon the available data, the classification criteria are

not met.

STOT - single exposure Based upon the available data, the classification criteria are

not met.

STOT - repeated exposure Based upon the available data, the classification criteria are

not met.

Aspiration hazard Based upon the available data, the classification criteria are

not met.

**Health Effects and Symptoms** 

Skin Contact No significant harmful effects anticipated. Eye Contact No significant harmful effects anticipated. Ingestion No significant harmful effects anticipated.

11.2 Information on other hazards Not applicable.

 Revision: 1
 Page: 4/6
 Date: Dec 15, 2023



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#### **SECTION 12: ECOLOGICAL INFORMATION**

**12.1 Toxicity** The product does not contain significant quantities of

ingredients that are environmentally toxic.

**12.2** Persistence and degradability The product is not biodegradable.

12.3 Bioaccumulative potential None anticipated.

**12.4 Mobility in soil** No information available.

12.5 Results of PBT and vPvB assessment Not applicable.

12.6 Endocrine disrupting properties Decomposition products; octyl phenol

12.7 Other adverse effects Not applicable.

#### **SECTION 13: DISPOSAL CONSIDERATIONS**

13.1 Waste treatment methods

Product: Dispose of as potentially biohazardous waste and in

compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved

waste-disposal company for information.

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.

Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

#### **SECTION 14: TRANSPORT INFORMATION**

14.1 UN number or ID number
 14.2 UN proper shipping name
 Not applicable
 Not applicable

14.3 Transport hazard class(es) Not classified as dangerous for transport.

14.4Packing groupNot applicable14.5Environmental hazardsNot applicable14.6Special precautions for userNot applicable

14.7 Maritime transport in bulk according to IMO
Not applicable

instruments

#### **SECTION 15: REGULATORY INFORMATION**

15.1 Safety, health and environmental None. regulations/legislation specific for the

substance or mixture

15.2 Chemical Safety Assessment Not applicable.

### **SECTION 16: OTHER INFORMATION**

#### LEGEND

STOT Specific Target Organ Toxicity
STEL Short Term Exposure Limit
LTEL Long Term Exposure limit
TWA Time Weighted Average
TLV Threshold Limit Value



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#### Classification code

Acute Tox. 1 Acute toxicity, Category 1
Acute Tox. 2 Acute toxicity: Category 2
Acute Tox. 4 Acute toxicity: Category 4
Eye Irrit. 2 Irritating to eyes. Category 2

STOT RE 2 Specific target organ toxicity — repeated exposure: Category 2
Aquatic Acute 1 Hazardous to the aquatic environment - Acute: Category 1
Aquatic Chronic 1 Hazardous to the aquatic environment - Chronic: Category 1
Aquatic Chronic 2 Hazardous to the aquatic environment - Chronic: Category 2

#### Hazard Statement(s)

H300: Fatal if swallowed. H302: Harmful if swallowed. H310: Fatal in contact with skin. H319: Causes serious eye irritation.

H373: May cause damage to organs through prolonged or repeated exposure.

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects. H411: Toxic to aquatic life with long lasting effects. EUH032: Contact with acids liberates very toxic gas.

#### References:

Raw material safety data sheets. ECHA Databases

#### **Additional Information**

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of 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 cannot guarantee that these are the only hazards that exist.