

SAFETY DATA SHEET (SDS)

Antigen Swab Quality Control Kit

Document #: MDX-SAL-SDS-045

Revision No: 000

Effective Date: Captured Electronically

1. IDENTIFICATION

1.1. **Product Name:**

Antigen Swab Quality Control Kit

1.2. **Product Part Number:**

MDXP0037 Respiratory Triplex (SARS-CoV-2 & Influenza A/B) Swab Quality Control Kit
MDXP0039 SARS-CoV-2 Swab Quality Control Kit
MDXP0041 Influenza A/B Swab Quality Control Kit
MDXP0043 RSV Swab Quality Control Kit
MDXP0045 SARS-CoV-2 & RSV Swab Quality Control Kit
MDXP0047 Universal Negative Swab Quality Control Kit

1.3. **GHS Product Identifier:**

No data available.

1.4. **Recommended Uses:**

The Antigen Swab Quality Control Kits are used to evaluate the performance of SARS-CoV-2, Influenza A, Influenza B, and/or RSV in antigen-based assays. It is recommended to run this panel: for technician training, to monitor the effect of laboratory environmental conditions, to examine test kit lot-to-lot consistency, and to follow operator variation. These controls should also be run according to your organization's quality system requirements for external Q.C. testing or by using the recommendations of the test kit manufacturer.

1.5. **Supplier Information:**

Company: MRN Diagnostics
101 Constitution Blvd
Franklin, MA 02038
United States
Telephone: 1-508-384-0033
Website: www.mrndx.com

1.6. **Emergency Contact:**

1-508-384-0033
Monday – Friday
8am-5pm EST

2. HAZARD IDENTIFICATION

2.1. **Classification of the substance or mixture:**

Although inactivated, this material has the potential to transmit infectious agents and should be handled with universal precautions for Biosafety Level 1. This product has SARS-CoV-2, Influenza A, Influenza B, and/or RSV viral strains that have been chemically inactivated to render them noninfectious.

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2.2. Signal Word:

Warning.

2.3. Hazard Statements:

Use Universal Precautions.

H302: Harmful if swallowed.

H319 - Causes serious eye irritation.

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

H401 - Toxic to aquatic life.

H411 - Toxic to aquatic life with long lasting effects.

EUH032: Contact with acids liberates very toxic gas.

2.4. Hazard Pictogram:

N/A

2.5. Precautionary Statement(s):

Biohazard: handle as if capable of transmitting infectious agents.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P273 Avoid release to the environment.

P280 Wear eye protection/ face protection.

P501 Dispose of contents/container to comply with local, state and federal regulations.

2.6. Other Hazards:

Contains chemically inactivated SARS-CoV-2, Influenza A, Influenza B, and/or RSV viral strains: exercise universal precautions.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Composition:

Buffered stabilized formulation containing the ingredients listed below.

Component/Chemical Name	Common Name / EC-No.	CAS-No.	Concentration
Polyoxyethylene(10) octylphenyl ether	Igepal CA-630	9002-93-1	<0.5%
Sodium Azide	Not Applicable	26628-22-8	<0.5%

3.2. Additional Information:

For full text of H phrases see section 16.

4. FIRST-AID MEASURES

4.1. Description of First-Aid Measures:

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4.1.1. If Inhaled:

Proceed to an area containing fresh air and keep at rest in a position comfortable for breathing.

4.1.2. In Case of Skin Contact:

Immediately wash thoroughly with warm water and antibacterial soap. Flush with water and seek medical attention.

4.1.3. In Case of Eye Contact:

Rinse immediately with copious amounts of water for several minutes. Use of an eye wash station preferable. Remove contact lenses if applicable and continue to rinse. Seek medical attention.

4.1.4. If Ingested:

Do not induce vomiting. Rinse mouth with water provided the person is conscious. Never give anything by mouth to an unconscious person. Seek medical attention.

4.2. Most Important Symptoms and Effect, Both Acute and Delayed:

No data available.

4.3. Recommendations for Immediate Medical Care and Special Treatment Needed:

Treat symptomatically.

5. FIRE-FIGHTING MEASURES

5.1. Suitable Extinguishing Media:

Use extinguishing measures and methods that are appropriate to local circumstances and the surrounding environment.

5.2. Specific Hazards Arising from the Chemical or Mixture:

Use water spray to cool fire-exposed containers.

5.3. Special Protective Actions for Fire-Fighters:

Wear self-contained breathing apparatus and protective suit.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures:

6.1.1. For Non-Emergency Personnel:

Avoid contact with skin and eyes. The use of laboratory coat, gloves and safety glasses is required.

6.1.2. For Emergency Responders:

Avoid contact with skin and eyes. The use of protective equipment is required.

6.2. Environmental Precautions:

Do not allow discharge into the environment.

6.3. Methods and Materials for Containment and Cleaning Up:

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Clean in accordance with applicable effective procedures and in compliance with state and federal regulations.

7. HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Avoid contact with skin and eyes. Wear personal protective equipment. Wash hands thoroughly after handling. Do not eat or drink while handling product.

7.2. Conditions for Safe Storage, Including any Incompatibilities

7.2.1. Storage Conditions:

Store in accordance to labeled or recommended storage temperature. Keep containers properly labeled.

7.2.2. Incompatible Products:

No data available.

7.2.3. Incompatible Materials:

No data available.

7.2.4. Recommended Storage:

Refer to product label, Certificate of Analysis or recommendation in relation to use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters:

This product contains substances with concentrations that are below occupational or national exposure limit values.

8.2. Appropriate Engineering Controls:

N/A

8.3. Personal Protective Equipment:

8.3.1. Eye/Face Protection:

Use of equipment for eye protection is required.

8.3.2. Skin/Body Protection:

Use of personal protective equipment is required, which includes the use of a laboratory coat and gloves.

8.3.3. Respiratory Protection:

In the case of insufficient ventilation wear suitable respiratory equipment.

8.3.4. Hand Protection:

Use of gloves is recommended. Inspect gloves prior to use to ensure adequate protection. Dispose of contaminated gloves after use in accordance with state/federal regulations and good laboratory practices. Wash hands thoroughly after handling.

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8.3.5. **Control of Environmental Exposure:**

N/A

8.3.6. **Pictograms**

N/A

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (Physical State, Color, etc.):

Dry swab. Coated tip color varies by control (Ex: red, blue, green, transparent).

Upper/lower flammability or explosive limits:

No data available.

Odor:

No data available.

Odor Threshold:

No data available.

Vapor Pressure:

No data available.

Vapor density:

No data available.

pH:

No data available.

Relative density:

No data available.

Melting point/freezing point:

No data available.

Solubility(ies):

No data available.

Initial boiling point and boiling range:

No data available.

Flash point:

No data available.

Evaporation rate:

No data available.

Flammability:

No data available.

Partition coefficient:

No data available.

Auto-ignition temperature:

No data available.

Decomposition temperature:

No data available.

Viscosity:

No data available

10. STABILITY AND REACTIVITY

10.1. **Reactivity:**

No data available.

10.2. **Chemical Stability:**

Stable under recommended storage conditions.

10.3. **Possibility of Hazardous Reactions:**

Violent reactions are possible with strong oxidizing agents.

10.4. **Conditions to Avoid:**

Avoid dust formation. Incompatible products. Heat, flames and sparks. Direct sunlight. Extremely high or low temperatures.

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10.5. Incompatible Materials:

Acids, Peroxides, Acid chlorides, Metals, Oxidizing agent, Strong bases

10.6. Hazardous Decomposition Products:

No data available.

11. TOXICOLOGICAL INFORMATION

11.1. Acute Toxicity:

Component	Oral	Dermal	Inhalation
Polyoxyethylene(10) octylphenyl ether	LD50 (Rat): 500-2,000 mg/kg	LC50 (Rat) >2,000 mg/kg	No data available.
Sodium Azide	LD50 (Rat): 27 mg/kg May be harmful if swallowed.	LD50 (Rabbit): 20 mg/kg Avoid contact with skin. Harmful in contact with skin. Avoid contact with eyes.	Toxic by inhalation. Avoid breathing dust or spray mist.

11.2. Skin Corrosion/Irritation:

No data available.

11.3. Serious Eye Damage/Irritation:

Causes serious eye damage.

11.4. Respiratory or Skin Sensitization

No data available.

11.5. Germ Cell Mutagenicity:

Mutagenic effects have occurred in experimental animals.

11.6. Carcinogenicity:

No data available.

11.7. Reproductive Toxicity:

No data available.

11.8. STOT-Single Exposure:

No data available.

11.9. STOT-Repeated Exposure:

Category 2

Target organs: Eyes, Skin, Respiratory system, Gastrointestinal tract (GI), Liver, Kidney, Central nervous system (CNS), Heart, spleen.

11.10. Aspiration Hazard:

No data available.

11.11. Additional Information:

Tumorigenic effects have been reported in experimental animals.

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12. ECOLOGICAL INFORMATION

12.1. Toxicity:

Component	Toxicity to fish	Toxicity to algae/aquatic plants	Toxicity to daphnia and other aquatic invertebrates	Toxicity to microorganisms
Polyoxyethylene (10) octylphenyl ether	LC50 (Danio rerio (zebra fish)): > 1-10 mg/l Exposure time: 96 h Method: OECD Test Guideline 203	LC50 (Desmodesmus subspicatus (green algae)): >= 10 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 GLP: yes	LC50 (Daphnia magna (Water flea)): 7.07 mg/l Exposure time: 48 h Method: Exposure type comment GLP: yes	(Pseudomonas putida): > 1,000 mg/l Exposure time: 17 h Method: DIN 38421 TEIL 8
Sodium Azide	LC50: = 0.7 mg/L, 96h (Lepomis macrochirus) LC50: = 0.8 mg/L, 96h (Oncorhynchus mykiss) LC50: = 5.46 mg/L, 96h flow-through (Pimephales promelas)	No data available.	No data available.	No data available.

12.2. Persistence and Degradability:

Soluble in water

Persistence is unlikely based on information available.

12.3. Bioaccumulative Potential:

Adverse ecological effects cannot be excluded in the event of improper handling or disposal.

12.4. Mobility in Soil:

No data available.

12.5. Other Adverse Effects:

No data available.

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13. DISPOSAL CONSIDERATIONS

13.1. Waste Disposal Recommendations:

Dispose of in accordance with state and federal regulations.

14. TRANSPORT INFORMATION

14.1. UN Number:

Not applicable.

14.2. UN Proper Shipping Name:

Not applicable.

14.3. Transport Hazard Class(es):

Not applicable.

14.4. Packing Group:

Not applicable.

14.5. Environmental Hazards:

Not applicable.

14.6. Bulk Transport:

Not applicable.

15. REGULATORY INFORMATION

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

In Vitro diagnostics medical devices directive 98/79/EC.

15.2. Chemical Safety Assessment:

Not applicable.

16. OTHER INFORMATION

16.1. Legend

STOT

Specific Target Organ Toxicity

Classification code:

Acute Tox. 3

Acute toxicity, Category 3

Acute Tox. 2

Acute toxicity, Category 2

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Acute Tox. 1	Acute toxicity, Category 1
Skin Corr. 1B	Skin corrosion/irritation; Category 1B
Skin Sens. 1A	Skin sensitizer, Category 1A
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

Hazard statement(s)

H300: Fatal if swallowed.
H301: Toxic if swallowed.
H310: Fatal in contact with skin.
H311: Toxic in contact with skin.
H314: Causes severe skin burns and eye damage.
H317: May cause an allergic skin reaction.
H331: Toxic if inhaled.
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.
EUH032: Contact with acids liberates very toxic gas.

16.2. SDS Prepared by:

Dr. Gregory R. Chiklis, Ph.D., MRN Diagnostics, LLC

16.3. Date of Preparation:

10-1-2025

16.4. Company Policy or Disclaimer:

The information herein is provided in good faith and is correct to the best of our knowledge and information currently available to us but makes no representation as to its completeness or accuracy. This safety data sheet is intended for use only as a guide for the appropriate precautionary handling of material by suitably trained personnel. Medical Research Networkx, LLC – MRN Diagnostics shall not be held liable for any damage, injury or loss resulting from handling or from contact with the above product. Users should make their own investigations to determine the suitability of information for their purposes.