

SAFETY DATA SHEET (SDS)

Liquid-Based External Run Control Pack

Document #: MDX-SAL-SDS-044

Revision No: 000

Effective Date: Captured Electronically

1. IDENTIFICATION

1.1. Product Name:

Liquid-Based External Run Control Pack

1.2. Product Part Number:

MDXP0036 Respiratory Triplex (SARS-CoV-2 & Influenza A/B) External Run Control Pack
MDXP0038 SARS-CoV-2 External Run Control Pack
MDXP0040 Influenza A/B External Run Control Pack
MDXP0042 RSV External Run Control Pack
MDXP0044 SARS-CoV-2 & RSV External Run Control Pack
MDXP0046 Universal Negative External Run Control Pack

1.3. GHS Product Identifier:

No data available.

1.4. Recommended Uses:

These Liquid-Based External Run Control Packs are used to evaluate the performance of SARS-CoV-2, Flu A, and Flu B assays. It is recommended to run these panels: for technician training, to monitor effect of laboratory environmental conditions, to examine test kit lot-to-lot consistency, and to follow operator variation. These controls should also be run following your organization's quality system requirements for external Q.C. testing or 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 2. This product has SARS-CoV-2, Influenza A, Influenza B, and/or RSV viral strains that have been chemically inactivated to render them noninfectious.

2.2. Signal Word:

Warning.

2.3. Hazard Statements:

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Use of universal precautions.

H302: Harmful if swallowed.

H317: May cause an allergic skin reaction.

H319 - Causes serious eye irritation.

H412: Harmful 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.

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
ProClin 950	Not Applicable	2682-20-4	<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:

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:

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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. Prevent leakage or spillage.

6.3. **Methods and Materials for Containment and Cleaning Up:**

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.

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- 7.2.2. **Incompatible Products:**
Strong oxidizing agents, Amines, Mercaptans, Reducing agents, Acids, Peroxides, Acid chlorides, Metals, Oxidizing agent
- 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.
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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:**
Ensure adequate ventilation or other engineering controls to reduce airborne levels.
- 8.3. **Personal Protective Equipment:**
- 8.3.1. **Eye/Face Protection:**
Use of equipment for eye protection is required. Avoid exposure to liquid splashes.
- 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 required. 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.
- 8.3.5. **Control of Environmental Exposure:**
Prevent product from entering drains.
- 8.3.6. **Pictograms**



9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (Physical State, Color, etc.): Viscous Liquid, Transparent.

Upper/lower flammability or explosive limits: No data available.

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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 possible with water.

10.4. Conditions to Avoid:

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

10.5. Incompatible Materials:

Strong oxidizing agents, Amines, Mercaptans, Reducing agents, Acids, Peroxides, Acid chlorides, Metals, Oxidizing agent

10.6. Hazardous Decomposition Products:

Nitrogen oxides (NO_x), Sodium oxides

11. TOXICOLOGICAL INFORMATION

11.1. Acute Toxicity:

Component	Oral	Dermal	Inhalation
ProClin 950	1,213 mg/kg (Calculation method)	2,444 mg/kg (Calculation method)	4 h - 1.11 mg/l - dust/mist (Calculation method)

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	Symptoms: If ingested, severe burns of the mouth and throat, as well as a danger of perforation of the esophagus and the stomach. LD50 Oral - 27 mg/kg (Rat)	LD50 Dermal - 20 mg/kg (Rabbit)	Symptoms: Possible symptoms:, mucosal irritations, Cough, Shortness of breath, Possible damages:, damage of respiratory tract. LC50 Inhalation - 0.054-0.52 mg/L (dust)
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:

Corrosive to eyes.

Mixture causes serious eye damage.

Risk of blindness!

11.4. Respiratory or Skin Sensitization

May cause allergic skin reaction.

11.5. Germ Cell Mutagenicity:

Mutagenic effects have occurred in experimental animals.

11.6. Carcinogenicity:

Did not show carcinogenic effects in animal experiments.

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.

Material is destructive to tissue of the mucous membranes and upper respiratory tract, eyes, and skin. Spasm, inflammation and edema of the larynx, spasm, inflammation and edema of the

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bronchi, pneumonitis, pulmonary edema, burning sensation, cough, wheezing, laryngitis, shortness of breath, headache, nausea, vomiting.

12. ECOLOGICAL INFORMATION

12.1. Toxicity:

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Component	Toxicity to fish	Toxicity to algae/aquatic plants	Toxicity to daphnia and other aquatic invertebrates	Toxicity to microorganisms
ProClin 950	LC50 (Oncorhynchus mykiss (rainbow trout)): 4.77 mg/l Exposure time: 96 h Test Type: flow-through test Analytical monitoring: yes Method: OECD Test Guideline 203 GLP: yes Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 0.85 mg/l Exposure time: 48 h Test Type: flow-through test Analytical monitoring: yes Method: OECD Test Guideline 202 GLP: yes	EC50 (Skeletonema costatum): 0.069 mg/l Exposure time: 96 h Test Type: static test Analytical monitoring: yes Method: OECD Test Guideline 201 GLP: yes M-Factor (Acute aquatic toxicity): 10	(Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0.044 mg/l Exposure time: 21 d Test Type: flow-through test Analytical monitoring: yes Method: OECD Test Guideline 211 GLP: yes M-Factor (Chronic aquatic toxicity): 1	EC50 (activated sludge): 41 mg/l Exposure time: 3 h Test Type: static test Method: OECD Test Guideline 209 GLP: yes
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:

No data available.

12.4. Mobility in Soil:

No data available.

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12.5. Other Adverse Effects:

No data available.

13. DISPOSAL CONSIDERATIONS

13.1. Waste Disposal Recommendations:

Material has undergone chemical inactivation. All human derived materials should be handled as if the material is infectious. The use of universal precautions is required by trained personnel. 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:

Labels Required: Exempt Human Specimen Label, per Classification section 3.6.2.2.3.8 of IATA DGR.

IATA Packaging Requirements: Packed in accordance with Classification section 3.6.2.2.3.8 of IATA DGR.

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.

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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

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:

10/2/2025

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.