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Safety Data Sheet

Section 1: Identification


Product Name: Clarity Strep A Strips
Synonyms: CD-STP25V and CD-STP50V
CAS Number: 26628-22-8
Manufacturer: Clarity Diagnostics, LLC.
Address: 1060 Holland Drive, Suite A, Boca Raton, FL 33487

Contact: (877) 485-7877

Recommended use: Clarity Strep A is a rapid immunochromatographic assay for the qualitative detection of group A streptococcal antigen directly from throat swab specimens. The test is intended for use in the physician's offices, hospitals, and clinical laboratories as an aid in the clinical diagnosis of group A streptococcal infection. The Test strips are supplied in a Vial Format.

Section 2: Hazard(s) Identification

GHS Classification:

Health	Environmental	Physical
Poison 	N/A	N/A

GHS Label:

Symbols	
Hazard Statements Do not Inhale or Swallow	Precautionary Statements Store at room temperature

Section 3: Composition/Information on Ingredients

Component	CAS Number	Weight
Sodium Azide	26628-22-8	9.9ng
See Section 8 For Exposure Limits		

Section 4: First-Aid Measures

Skin: If contact with this product leads to reddening, inflammation, or irritation, flush the exposed area with running water for 15 minutes. If irritation continues, seek medical attention.

Eye: Although no adverse health reactions are expected from the normal use of this product, it is recommended to flush eyes with water and seek medical advice whenever there has been a potential injury to the eye.

Inhalation: If breathing becomes difficult, have victim escorted to obtain fresh air. Seek medical attention.

Ingestion: Though not a likely route of occupational exposure, ingestion of this product may cause choking, vomiting, or nausea.

Medical Information: None

Section 5: Fire-Fighting Measures

Suitable Extinguishing Media: Use fire extinguishing media appropriate for site conditions.

Fire Fighting Procedures: Use CO₂, Foam, or Water.

Unusual Fire and Explosion Hazards: None Known

Combustion Products: None known

Section 6: Accidental Release Measures

Accidental release measures: Use an absorbent material to contain/pick up the spilled solution. Place all contaminated disposables into a suitable container, seal, label, and hold for disposal.

Section 7: Handling and Storage

Handling: Handle and store vials as directed in the package insert.

Storage: Should be stored at 2-30°C (35-86°F) in its canister, out of direct sunlight. Do not Freeze. Kit contents are stable until the expiration date printed on the outer box

Section 8: Exposure Controls/Personal Protection

Exposure Limits

Engineering Controls: Eye wash stations and deluge showers.

Personal Protective Equipment (PPE): Wear appropriate eye protection to prevent eye contact. Wear appropriate body protection to prevent skin contact. Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.

Ventilation: Supplemental ventilation is not required for the normal use of this product. Normal

ventilation is the standard to be met.

Section 9: Physical and Chemical Properties

Flashpoint: N.A

Auto Ignition Temperature: N.A

Boiling Point: N.A

Melting Point: <0.1

Vapor Pressure: <0.1

Vapor Density (Air=1):

% Solubility in Water: N.A

Pour Point: Not Available

Molecular Formula: N.A

Odor/Appearance: Red, Odorless

Lower Flammability Limit: N.A

Upper Flammability Limit: N.A

Specific Gravity: = N.A. (Water=1)

% Volatile: N.A

Evaporation Rate (Water=1): N.A

Viscosity: Not Available.

Octanol/Water Partition Coefficient: Not Available

pH: Not Available

Molecular Weight: N/A

Section 10: Stability and Reactivity

Stability and reactivity: This product is stable up to the expiration date printed on the label if kept at 35-86°F (2-30°C) Non- reactive within this kit.

Hazardous Reactions/Decomposition Products: Will not occur/None known

Section 11: Toxicological Information

Signs and Symptoms of Overexposure: No effects of overexposure

Acute Effects: None

Eye Contact: May cause conjunctival irritation.

Skin Contact: May cause reddening. May cause irritant skin reaction.

Inhalation: Not Considered Health Risk

Ingestion: May cause irritant conditions if swallowed.

Target Organ Effects: None

Chronic Effects: None

Medical Conditions Aggravated by Exposure: N/A

Acute Toxicity Values: N/A

Section 12: Ecological Information* (non-mandatory)

- No ecological information available

Section 13: Disposal Considerations* (non-mandatory)

Appropriate Methods of Disposal	Disposal should be made in accordance with existing disposal practices. Observe all Federal, State and Local law requirements.
European Community (EC) Consideration	Use appropriate waste codes based on ingredients.

Section 14: Transport Information* (non-mandatory)

Transport Precautions	Consult applicable regulations when transporting this product
Additional Information	Follow the instructed guidelines listed in package for proper transportation.

Section 15: Regulatory Information* (non-mandatory)

European Labeling in accordance with EC Directives	
Hazard Symbols	N.A
Safety Phrases	Keep out of the reach of children
Risk Phrases	None
Additional Information	Consult country codes for specific requirements

Section 16: Other Information

Other Precautions: No other precautions needed. Clarity provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the materials contained in this kit by a properly trained person using this product. Clarity shall not be held liable for any damage resulting from handling or use.

This product is for in vitro diagnostics use only.

*Note: Since other Agencies regulate this information, OSHA will not be enforcing Sections 12 through 15(29 CFR 1910.1200(g)(2)).