Section 1 – Product and Company Identification

Manufacturer Information

Quidel Corporation
2005 East State Street, Suite 100
Athens, OH 45701
Phone: 1.800.874.1517
Fax: 1.740.592.9820
Emergency #: 1.866.519.4752
Web: quidel.com
E-mail: qehs@quidel.com

Product Information

Product Name: Solana Strep Complete Assay (Catalog #: M305)

Intended Use: An in vitro diagnostic test, using isothermal amplification technology (helicase-dependent amplification, HDA), for the qualitative detection and identification of Streptococcus pyogenes (Group A β-hemolytic Streptococcus) and Streptococcus dysgalactiae (pyogenic Group C and G β-hemolytic Streptococcus) nucleic acids isolated from throat swab specimens obtained from patients with signs and symptoms of pharyngitis, such as a sore throat. Intended for use only with the Solana® instrument.

Components: Lysis Buffer (0.5 mL), Dilution Buffer (0.5 mL), GAS Reaction Tubes (25 µL), C/G Reaction Tubes (25 µL)

Section 2 – Hazards Identification

Emergency Overview

<table>
<thead>
<tr>
<th>Kit Component</th>
<th>OSHA Hazards</th>
<th>Target Organs</th>
<th>GHS Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lysis Buffer (1.0% Triton X-100)</td>
<td>Irritant</td>
<td>Eye</td>
<td>Skin Irritation (Category 2A) Chronic Aquatic Toxicity (Category 3)</td>
</tr>
</tbody>
</table>

GHS Classification and Label Elements

Component: Lysis Buffer (1.0% Triton X-100)

Pictogram: Warning

Hazard Statements:
- H319 Causes serious eye irritation.
- H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements:
- P264 Wash hands thoroughly after handling.
- P273 Avoid release to the environment.
- P280 Wear eye protection / face protection.
- P305+P351+P338: IF EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P337+P313: If eye irritation persists: Get medical attention.

Supplemental Hazard Statements:
1. Follow Universal Precautions when working with this kit.
2. Maybe harmful if swallowed.

Section 3 – Composition / Information on Ingredients

<table>
<thead>
<tr>
<th>Component</th>
<th>Chemical Name</th>
<th>CAS #</th>
<th>EINECS #</th>
<th>Conc. (%)</th>
<th>Component Volume</th>
<th>Chemical Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lysis Buffer</td>
<td>Triton X-100</td>
<td>9002-93-1</td>
<td>618-344-0</td>
<td>1.0</td>
<td>0.5 mL</td>
<td>Acute Tox. 4; Eye Irrit. 2A; Aquatic Acute 2; Aquatic Chronic 2; H302, H319, H411</td>
</tr>
<tr>
<td>Dilution Buffer</td>
<td>Glycerol</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>&lt;5.5</td>
<td>0.5 mL</td>
<td>--</td>
</tr>
</tbody>
</table>
### Section 4 – First Aid Measures

**General Advice**
Move out of exposure area. Consult a physician. Show this safety data sheet to the doctor in attendance, as necessary.

- **If inhaled:** Move the person to fresh air and support breathing as required.
- **In case of skin contact:** Wash affected area with soap and water. Seek medical advice if irritation develops.
- **In case of eye contact:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists get medical attention.
- **If swallowed:** Never give anything by mouth to an unconscious person. Rinse mouth with water. Seek medical advice if irritation develops.
- **Note to Physicians:** Treat symptomatically.

### Section 5 – Fire Fighting Measures

**General Advice**
Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to extinguish a fire.

- **Extinguishing Media:** For small fires, use dry chemical, water spray, carbon dioxide or alcohol-resistant foam.
- **General Fire Hazards:** The components within this kit will not significantly contribute to the intensity of a fire.
- **Hazardous Combustion Products:** No data available
- **Fire Fighting Equipment:** Firefighters should wear full protective gear when responding to fires.

### Section 6 – Accidental Release Measures

**General Advice**
Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. Large spills of the solutions, controls, buffers or reagents contained within this kit are unlikely.

- **Personal Precautions:** Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills of the solutions, controls or reagents within this kit. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from the spill area.
- **Materials and Methods for Clean-Up:** Soak up with inert absorbent material (e.g., paper towel, etc.). Thoroughly wash the area with soap and water after a spill or release clean-up.
- **Recovery and Neutralization:** Collect spilled material and clean-up supplies and place in sealed container for disposal. Refer to Section 13 for disposal guidance.
- **Environmental Precautions:** Contain spill to prevent migration to drains, sewers or open water sources. Discharge into the environment must be avoided.
Section 7 – Handling and Storage

Specific Use: For *in vitro* diagnostic use only. Not for use by the general public.

Precautions for Safe Handling
As with all chemical and biological substances, avoid getting this solution ON YOU or IN YOU. Wash exposed areas thoroughly after using this solution. Do not eat or drink while using this solution. This solution should be handled only by qualified clinical or laboratory employees trained on the use of this solution and who are familiar with the potential hazards. Universal Precautions should be followed when handling and working with this solution. Keep out of reach of the general public.

Conditions for Safe Storage: To maintain efficacy, store according to the kit specific Technical Data Sheet.

Incompatibilities: To maintain efficacy, store according to the kit specific Technical Data Sheet.

Section 8 – Exposure Controls and Personal Protection

Exposure Limits: No data available for the components in this kit.

Exposure Controls:

**Engineering Measures**: Use with adequate ventilation.

**Personal Protective Equipment**

- **Respiratory Protection**: None needed under normal conditions of use.
- **Hand Protection**: Handle with appropriately rated chemical resistant gloves. Gloves should be inspected prior to use. Use proper glove technique to remove gloves to avoid contact with skin. Wash hands after handling the components within this kit.
- **Eye Protection**: Wear safety glasses with side shields or goggles to prevent eye contact.
- **Skin and Body Protection**: Use body protection appropriate for the task. A laboratory coat is recommended.
- **Hygiene Measures**: Wash hands before and after use and at the end of the workday.

**Environmental Exposure Controls**
No special environmental controls are required.

Section 9 – Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Lysis Buffer</th>
<th>Dilution Buffer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting Point (°C)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Specific Gravity (H₂O = 1)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (mm Hg)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (Air = 1)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Ether = 1)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>Neutral</td>
<td>Neutral</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Soluble</td>
<td>Soluble</td>
</tr>
<tr>
<td>Appearance and Odor</td>
<td>Clear, Odorless</td>
<td>Clear, Odorless</td>
</tr>
</tbody>
</table>
Section 10 – Stability and Reactivity

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Lysis Buffer</th>
<th>Dilution Buffer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component Stability</td>
<td>Stable</td>
<td>Stable</td>
</tr>
<tr>
<td>Hazard Reaction Potential</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Materials to Avoid</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>

Section 11 – Toxicological Information

Acute Toxicity

**Component Analysis – LD50 / LC50 / Irritation** (No data available for specific kit components)

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>RTECS #</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triton X-100</td>
<td>9002-93-1</td>
<td>MD0907700</td>
<td>Oral LD&lt;sub&gt;50&lt;/sub&gt; Rat 1800 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inhalation LC&lt;sub&gt;50&lt;/sub&gt; No data available</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dermal LD&lt;sub&gt;50&lt;/sub&gt; No data available</td>
</tr>
</tbody>
</table>

**Potential Health Effects:** Specimen-Stabilizing Solution (A9576)

- **Skin Corrosion/ Irritation:** No data available  
  Inhalation: May cause respiratory tract irritation.
- **Serious Eye Damage / Irritation:** No data available  
  Skin: May cause skin irritation upon contact.
- **Respiratory or Skin Sensitization:** No data available  
  Eyes: May cause serious eye irritation.
- **Generative Cell Mutagenicity:** No data available  
  Ingestion: May be harmful if swallowed.

**Carcinogenicity**

No components within this solution present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by the IARC, ACGIH, NTP or OSHA.

**Reproductive Toxicity** No data available

**Teratogenicity** No data available

**Specified Target Organ General Toxicity (GHS)**

- **Synergistic Effects** No data available

  - **Single Exposure (GHS):** No data available
  - **Repeated Exposure (GHS):** No data available

**Aspiration Respiratory Organs Hazard**

None anticipated under product use conditions.

**Signs and Symptoms of Exposure**

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for this solution.

**Additional Information** None
Section 12 – Ecological Information

Ecotoxicity
No data available

Persistence / Degradability
No data available

Bioaccumulation
No data available

Mobility in Soil
No data available

PBT and vPvB Assessment
Assessment not available as chemical safety assessment not required or not conducted.

Other Adverse Effects
An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Avoid release to the environment.

Section 13 – Disposal Considerations

Waste Disposal Instructions
Utilize appropriate personal protective equipment and spill control when handling wastes generated from using this kit. Do not discharge any of the solutions, reagents or controls into drains, water courses or onto the ground.

Disposal of Product and Contaminated Packaging
Dispose of waste materials, unused components and contaminated packaging in compliance with country, federal, state and local regulations. If unsure of the applicable regulatory requirements, contact a licensed professional waste disposal service to dispose of this material.

Section 14 – Transportation Information

U.S. Department of Transportation (DOT)
This kit is not regulated for transport.

International Air Transportation (IATA)
This kit is not regulated for transport.

International Maritime Dangerous Goods (IMDG)
This kit is not regulated for transport.

Section 15 – Regulatory Information

Regulatory Information
U.S. Federal Regulations

OSHA Hazards
Lysis Buffer: Irritant

SARA 302
The following chemicals are subject to reporting levels established by SARA Title III, Section 302:
No chemicals in this solution are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313
The following chemicals are subject to reporting levels established by SARA Title III, Section 313:
This solution does not contain any chemical components that exceed threshold (De Minimis) reporting levels established by SARA Title III, Section 313

SARA 311/312
Triton X-100
CAS#: 9002-93-1
Acute Health Hazard
Section 15 – Regulatory Information (cont’d)

State Regulations

The following chemical(s) appear on one or more of the following state hazardous substances lists:

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>CA</th>
<th>MA</th>
<th>MN</th>
<th>NJ</th>
<th>PA</th>
<th>RI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triton X-100</td>
<td>9002-93-1</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

**California Prop 65:** This solution does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

Canadian – WHMIS IDL

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>Minimum Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triton X-100</td>
<td>9002-93-1</td>
<td>1%</td>
</tr>
</tbody>
</table>

Additional Regulatory Information

Safety, Health and Environmental regulations/legislation specific for the mixture:

No data available

Chemical Safety Assessment:

Not completed for this components contained within this kit.

<table>
<thead>
<tr>
<th>HMIS Kit Classification:</th>
<th>NFPA Kit Classification:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Hazard: 1</td>
<td>Health Hazard (blue): 1</td>
</tr>
<tr>
<td>Chronic Health Hazard: *</td>
<td>Fire Hazard (red): 0</td>
</tr>
<tr>
<td>Flammability: 0</td>
<td>Reactivity (yellow): 0</td>
</tr>
<tr>
<td>Physical Hazard: 0</td>
<td>Special Hazards (white): None</td>
</tr>
</tbody>
</table>

*Use additional care when handling the components within this kit.

Section 16 – Other Information

Text of H-code(s) mentioned in Section 3:

- **Acute Tox.** Acute Toxicity H302 Harmful if swallowed.
- **Aquatic Acute** Acute Aquatic Toxicity H319 Causes serious eye irritation.
- **Aquatic Chronic** Chronic Aquatic Toxicity H402 Harmful to aquatic life.
- **Eye Irrit.** Eye Irritation H411 Toxic to aquatic life with long lasting effects.
- H412 Harmful to aquatic life with long lasting effects.

PREPARED BY: Quidel Corporation
12544 High Bluff Drive, Suite 200, San Diego, CA 92130

SUPERCEDES: --

REVISIONS: New

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