Section 1 – Product and Company Identification

1.1 Manufacturer Information
Quidel Corporation
2005 East State Street, Suite 100
Athens, OH 45701
Phone: 1.800.874.1517
Fax: 1.740.592.9820
Emergency (24-Hour): 1.866.519.4752

2.1 Product Information
Product Name: Lyra Direct Strep Assay (Catalog #: M112)
Intended Use: The Lyra Direct Strep Assay is a multiplex Real-time PCR assay for the qualitative detection and identification group A streptococcus nucleic acids and pyogenic group C and G streptococcal nucleic acids isolated from throat swab specimens. This assay is for professional use only.
Components: Rehydration Solution (M5003), Lyra Direct Step Master Mix (M5060) and Lyra Direct Strep Process Buffer (M5061)

Section 2 – Hazard Identification

2.1 Classification of the Substance of Mixture
Not a hazardous substance or mixture.

2.2 GHS Label Elements, including Precautionary Statements
Not a hazardous substance or mixture.

2.3 Hazards Not Otherwise Classified (HNOC) or not covered by GHS
None

Section 3 – Composition / Information on Ingredients

3.1 Mixtures
- Contains non-hazardous quantities of proprietary ingredients according to OSHA (29 CFR 1910.1200).
- Not a hazardous mixture according to Regulation (EC) No. 1272/2008.

3.2 No chemicals need to be disclosed according to the applicable regulations for the components in this kit.

Section 4 – First Aid Measures

4.1 Description of First Aid Measures
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.

4.2 Most Important Symptoms and Effects (both acute and delayed)
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed
No specific measures identified.
Section 5 – Fire Fighting Measures

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

5.1 Suitable Extinguishing Media
   For small fires, use dry chemical, carbon dioxide or alcohol-resistant foam.

5.2 Special Hazards Arising from the Substance or Mixture
   Nature of decomposition products not known.

5.3 General Fire Hazards
   The components within this kit will not significantly contribute to the intensity of a fire.

5.4 Fire Fighting Equipment
   Firefighters should wear full protective gear when responding to fires.

Section 6 – Accidental Release Measures

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. A large spill of the components contained within this kit is unlikely.

6.1 Personal Precautions
   Avoid breathing vapors, mist or gas.

6.2 Environmental Precautions
   Contain spill to prevent migration to drains, sewers or open water sources. Discharge to the environment must be avoided.

6.3 Methods and Materials 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.

6.4 Recovery and Neutralization
   Collect spilled material and clean-up supplies and place in a sealed container for disposal. Refer to Section 13 for disposal guidance.

Section 7 – Handling and Storage

7.1 Specific Use
   For professional use only – Not for use by the general public.

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

7.3 Conditions for Safe Storage (including any incompatibilities)
   To maintain efficacy, store according to the package insert instructions.

7.4 Incompatibilities
   To maintain efficacy, store according to the package insert instructions.

Section 8 – Exposure Controls and Personal Protection

8.1 Exposure Limits
   No data available for the components within this kit.

8.2 Exposure Controls
   Engineering Measures
   Use with adequate ventilation.

   Personal Protective Equipment
   Respiratory Protection
   None needed under normal conditions of use.

   Skin 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.
Section 8 – Exposure Controls and Personal Protection (cont’d)

**Eye Protection**
Wear safety glasses with side shields or goggles to prevent eye contact.

**Body Protection**
Use body protection appropriate for the task. A laboratory coat is recommended.

**Hygiene Measures**
Wash hands before use, after use and at the end of the workday.

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

8.4 **Special Notes**
No data available.

Section 9 – Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Rehydration Solution</th>
<th>Direct Strep Process Buffer</th>
<th>Direct Strep Master Mix</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</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>
<td>No data available</td>
</tr>
<tr>
<td>Specific Gravity (H₂O = 1)</td>
<td>No data available</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>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (Air = 1)</td>
<td>No data available</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>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>Neutral</td>
<td>Neutral</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Soluble</td>
<td>Soluble</td>
<td>Soluble</td>
</tr>
<tr>
<td>Appearance and Odor</td>
<td>Clear liquid, mild odor</td>
<td>Clear liquid, mild odor</td>
<td>White powder, odorless</td>
</tr>
</tbody>
</table>

Section 10 – Stability and Reactivity

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Rehydration Solution</th>
<th>Direct Strep Process Buffer</th>
<th>Direct Strep Master Mix</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component Stability</td>
<td>Stable</td>
<td>Stable</td>
<td>Stable</td>
</tr>
<tr>
<td>Hazard Reaction Potential</td>
<td>No data available</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>
<td>No data available</td>
</tr>
<tr>
<td>Materials to Avoid</td>
<td>No data available</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>
<td>No data available</td>
</tr>
</tbody>
</table>

Section 11 – Toxicological Properties

11.1 **Information on Toxicological Effects**

- **Acute Toxicity**
  No data available

- **Skin Corrosion / Irritation**
  No data available

- **Respiratory or Skin Sensitization**
  No data available

- **Generative Cell Mutagenicity**
  No data available

- **Carcinogenicity**
  No component of this kit present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by the ACGIH, IARC, NTP or OSHA.

- **Reproductive Toxicity**
  No data available

- **Teratogenicity**
  No data available
Section 11 – Toxicological Properties (cont’d)

Specified Target Organ Toxicity

Single Exposure: No data available
Repeated Exposure: No data available

Aspiration Hazard: No data available

Potential Health Effects

Inhalation: May cause respiratory tract irritation.
Skin: May cause skin irritation upon contact.

Ingestion: May be harmful if swallowed.
Eyes: May cause eye irritation.

11.2 Signs and Symptoms of Exposure
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for the components within this kit.

11.3 Additional Information
No data available

Section 12 – Ecological Information

12.1 Toxicity
No data available

12.2 Persistence and Degradability
No data available

12.3 Bioaccumulative Potential
No data available

12.4 Mobility in Soil
No data available

12.5 PBT and vPvB Assessment
No data available

12.6 Other Adverse Effects
An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Section 13 – Disposal Considerations

13.1 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.

13.2 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

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

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

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

Section 15 – Regulatory Information

15.1 U.S. Federal Regulations

OSHA Hazards
None

SARA 302
The following chemicals are subject to reporting levels established by Sara Title III, Section 302:
None

SARA 313
The following chemicals are subject to reporting levels established by SARA Title III, Section 313:
None

SARA311/312 Hazards
None
Section 15 – Regulatory Information (cont’d)

15.2 State Regulations

The following chemicals appear on one or more of the following state hazardous substance 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>
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</tbody>
</table>

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

15.3 Canadian – WHMIS Ingredient Disclosure List

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>Minimum Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>--</td>
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</tr>
</tbody>
</table>

15.4 Additional Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Mixture: No data available

Chemical Safety Assessment: Not completed for the components contained within this kit.

HMIS Kit Classification:

- Health Hazard: 1
- Chronic Health Hazard: *
- Flammability: 0
- Physical Hazard: 0

NFPA Kit Classification:

- Health Hazard (blue): 1
- Fire Hazard (red): 0
- Reactivity (yellow): 0
- Special Hazards (white): None

*Use additional care when handling this kit.

Section 16 – Other Information

Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, European Communities Safety Data Sheets Directive, Canadian Controlled Products Regulations, UK Chemical Hazard information and Packaging Regulations, and UN Globally Harmonized System of Classification and Labeling of Chemicals.

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

SUPERSEDES: January 9, 2014

REVISONS: Change to format of SDS.

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