Section 1 – Product and Company Identification

Manufacturer Information
Quidel Corporation
10165 McKellar Court
San Diego, CA 92121
Phone: 1.800.874.1517
Fax: 1.858.453.4338
Web: quidel.com
E-mail: qehs@quidel.com

Product Information
Product Name: QuickVue In-Line Strep A Test (Catalog #: 00343 and 00346)
Intended Use: The QuickVue In-Line Strep A test allows for the rapid detection of Group A Streptococcal antigen directly from patient throat swab specimens. The test is intended for professional and laboratory use as an aid in the diagnosis of Group A Streptococcal infection. This kit is for in vitro diagnostic use only.
Components: Kit is composed of individually pouched Test Cassette, Extraction Solution Bottles (contains Sodium Nitrite and Acetic Acid), Sterile Rayon-tipped Throat Swabs, Positive Control Swab (heat inactivated Group A Streptococcus) and Negative Control Swab (heat inactivated Group C Streptococcus).

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>
</table>
| Extraction Solution (Sodium Nitrite, 27.6%) | Toxic, Irritant | Eyes and skin | Acute Toxicity, Oral (Category 4)  
|               |                  |                   | Eye Irritation (Category 2A)                    
|               |                  |                   | Acute Aquatic Toxicity (Category 1)            |

GHS Label Elements and Precautionary Statements

<table>
<thead>
<tr>
<th>Component</th>
<th>Pictogram</th>
<th>Signal Word</th>
<th>Hazard Statements</th>
<th>Precautionary Statements</th>
</tr>
</thead>
</table>
| Extraction Solution (Sodium Nitrite, 27.6%) | ![Pictogram] | Warning | H302 Harmful if swallowed. 
H319 Causes serious eye irritation. 
H400 Very toxic to aquatic life. | P280 Wear protective gloves and eye protection.  
P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |

Supplemental Hazard Statements
1. Follow Universal Precautions when working with the components within this kit.
2. Wash skin thoroughly after handling. (P264)
3. Do not eat, drink or smoke when using this kit. (P270)
4. Avoid release to the environment. (P273)
Section 3 – Composition / Information on Ingredients

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>EINECS #</th>
<th>Concentration (%)</th>
<th>Component Volume</th>
<th>Chemical Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Nitrite</td>
<td>7632-00-0</td>
<td>231-555-9</td>
<td>27.6</td>
<td>&lt;0.4 mL</td>
<td>Ox. Sol.3; Acute Tox. 3; Eye Irrit. 2A, Acute Aq. 1; H272, H301, H319, H400</td>
</tr>
<tr>
<td>Acetic Acid</td>
<td>64-19-7</td>
<td>200-580-7</td>
<td>1.2</td>
<td>&lt;0.5 mL</td>
<td>Flam. Liq. 3; Skin Corr. 1A; Eye Dam. 1; H226, H314, H318</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.

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: Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Seek medical advice if irritation develops.

Most important symptoms and effects, both acute and delayed
Symptoms after ingestion: Harmful if swallowed.

Indication of any immediate medical attention and special treatment needed
No specific measures identified.

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.

Suitable Extinguishing Media: For small fires, use dry chemical, 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. A large spill of the Extraction Solution contained within this kit is unlikely.

Personal Precautions (e.g., PPE): Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills of the Extraction Solution. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from 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 a 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 to 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 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.

Conditions for Safe Storage: To maintain efficacy, store according to the package insert instructions.

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

Section 8 – Exposure Controls and Personal Protection

Exposure Limits: No data available for the components within 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 use, after use and at the end of the workday.

Environmental Exposure Controls

No special environmental controls are required

Special Notes

When activating the Extraction Solution (by breaking the glass ampoule of 1.2% Acetic Acid and mixing with the 27.6% Sodium Nitrite), the initial chemical reaction will create nitrogen dioxide and Nitric Oxide as reaction products.
### Section 9 – Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Extraction Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sodium Nitrite (27.6%)</td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Specific Gravity (H₂O = 1)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (mm Hg)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (Air = 1)</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Ether = 1)</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>8.6</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Soluble</td>
</tr>
<tr>
<td>Appearance and Odor</td>
<td>Liquid, yellow with no odor</td>
</tr>
</tbody>
</table>

### Section 10 – Stability and Reactivity

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Extraction Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sodium Nitrite (27.6%)</td>
</tr>
<tr>
<td>Component Stability</td>
<td>Stable</td>
</tr>
<tr>
<td>Hazard Reaction Potential</td>
<td>No data available</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>No data available</td>
</tr>
<tr>
<td>Materials to Avoid</td>
<td>No data available</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
<td>No data available</td>
</tr>
</tbody>
</table>

### Section 11 – Toxicological Information

#### Acute Toxicity

**Component Analysis – LD50 / LC50**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>RTECS #</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Nitrite</td>
<td>7632-00-0</td>
<td>RA1225000</td>
<td>Inhalation LC50 Rat 5.5 mg/L 4 hr 85 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Oral LD50 Rat 11.4 mg/L 4 hr 3310 mg/kg</td>
</tr>
<tr>
<td>Acetic Acid</td>
<td>64-19-7</td>
<td>AF1225000</td>
<td>Inhalation LC50 Rat 11.4 mg/L 4 hr 3310 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Oral LD50 Rat 3310 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dermal LD50 Rabbit 1060 mg/kg</td>
</tr>
</tbody>
</table>

**Potential Health Effects**

- **Skin Corrosion/Irritation:** No data available
- **Serious Eye Damage/Irritation:** No data available
- **Respiratory or Skin Sensitization:** No data available
- **Generative Cell Mutagenicity:** No data available
- **Inhalation:** May cause respiratory tract irritation.
- **Skin:** May cause skin irritation upon contact.
- **Eyes:** May cause eye irritation.
- **Ingestion:** No data available
## Section 11 – Toxicological Information (cont’d)

### Carcinogenicity

<table>
<thead>
<tr>
<th>IARC</th>
<th>Extraction Solution</th>
<th>2A - Group 2A: Probably carcinogenic to humans (Sodium Nitrite)</th>
</tr>
</thead>
</table>

The Extraction Solution does not contain any chemicals present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by the ACGIH, NTP or OSHA.

### Reproductive Toxicity

No data available

### Teratogenicity

No data available

### Specified Target Organ General Toxicity

<table>
<thead>
<tr>
<th>Single Exposure (GHS)</th>
<th>Repeated Exposure (GHS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>

### Aspiration Respiratory Organs Hazard

None anticipated under product use conditions.

### Synergistic Effects

No data available

### 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.

### Additional Information

Liver – irregularities – Based on Human Evidence (Sodium Nitrite).

## Section 12 – Ecological Information

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Mobility in Soil</th>
</tr>
</thead>
<tbody>
<tr>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Persistence / Degradability</th>
<th>No data available</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Bioaccumulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>No data available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PBT and vPvB Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not available as chemical safety assessment not required / not conducted.</td>
</tr>
</tbody>
</table>

### Other adverse effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Toxic to aquatic life.

## 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 the Extraction Solution 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 the authorities for information.

## 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.
Regulatory Information

U.S. Federal Regulations

OSHA Hazards Reagent Solution: Toxic, Irritant

SARA 302 The following chemicals are subject to reporting levels established by SARA Title III, Section 302:
No chemicals in this kit 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:
Sodium Nitrite CAS#: 7632-00-0 Revision Date: 2007-07-01

SARA 311/312 Sodium Nitrite CAS#: 7632-00-0 Acute Health Hazard / Chronic Health Hazard
Acetic Acid CAS#: 64-19-7 Fire Hazard, Acute Health Hazard, Chronic Health Hazard

State Regulations

The following chemicals 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>Sodium Nitrite</td>
<td>7632-00-0</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Acetic Acid</td>
<td>64-19-7</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</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.

Canadian - WHMIS IDL

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>Minimum Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Nitrite</td>
<td>7632-00-0</td>
<td>1%</td>
</tr>
<tr>
<td>Acetic Acid</td>
<td>64-19-7</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 the components contained within this kit.

HMIS Kit Classification:

- Health Hazard: 2
- Chronic Health Hazard: *
- Flammability: 0
- Physical Hazard: 0

NFPA Kit Classification:

- Health Hazard (blue): 2
- Fire Hazard (red): 0
- Reactivity (yellow): 0
- Special Hazards (white): None

*Use additional care when handling this kit.
Section 16 – Other Information

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

SUPERCEDES: December 2, 2013

REVISIONS: Updated template, updated to Acute Aquatic Toxicity (Category 1), added environmental hazard pictogram, updated supplemental hazard statements in Section 2; updated Section 3 with chemical classification for raw material; removed specific exposure limit data in Section 8; updated to include IARC 2A and Additional Information in Section 11; removed reference to EU Directive 67/548/EEC danger symbols, risk phrases and safety phrases, and included HMIS and NFPA ratings in Section 15; added text of H-codes and removed legend in Section 16.

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