QuickVue Dipstick Strep A Test

Safety Data Sheet

Revision Date: April 27, 2016

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® Dipstick Strep A Test (Catalog #: 20108, 20125, 20152)
Intended Use: The QuickVue Dipstick Strep A test is intended for the rapid, qualitative detection of Group A Streptococcal antigen from throat swabs or confirmation of presumptive Group A Streptococcal colonies recovered from culture. 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 Dipsticks, Extraction Reagent A (Sodium Nitrite), Extraction Reagent B (Acetic Acid), Sterile Rayon-tipped Throat Swabs, Positive Control (heat inactivated Group A Streptococcus) and Negative Control (heat inactivated Group C Streptococcus).

Section 2 – Hazards Identification

Emergency Overview

<table>
<thead>
<tr>
<th>Component</th>
<th>OSHA Hazards</th>
<th>Target Organs</th>
<th>GHS Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extraction Reagent A (Sodium Nitrite, 27.6%)</td>
<td>Toxic, Irritant</td>
<td>Eyes, Liver</td>
<td>Acute Toxicity, Oral (Category 4) Eye Irritation (Category 2A) Acute Aquatic Toxicity (Category 1)</td>
</tr>
<tr>
<td>Negative Control (Microcide III, 0.3%)</td>
<td>Irritant, Sensitizer</td>
<td>Skin, eyes</td>
<td>Eye Irritation (Category 2A) Skin Irritation (Category 2) Skin Sensitizer (Category 1)</td>
</tr>
</tbody>
</table>

GHS Label Elements and Precautionary Statements

<table>
<thead>
<tr>
<th>Component</th>
<th>Pictogram</th>
<th>Hazard Statements</th>
<th>Precautionary Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extraction Reagent A (Sodium Nitrite, 27.6%)</td>
<td>![WARNING]</td>
<td>H302 Harmful if swallowed. H319 Causes serious eye irritation. H400 Very toxic to aquatic life.</td>
<td>P280 Wear protective gloves and eye clothing. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</td>
</tr>
<tr>
<td>Negative Control (Microcide III, 0.3%)</td>
<td>![Warning]</td>
<td>H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation.</td>
<td>P261 Avoid breathing mist or spray. 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.</td>
</tr>
</tbody>
</table>
Section 2 – Hazards Identification (cont’d)

**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>Component</th>
<th>Chemical Name</th>
<th>CAS #</th>
<th>EINECS #</th>
<th>Conc. (%)</th>
<th>Component</th>
<th>Chemical Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extraction Reagent A</td>
<td>Sodium Nitrite</td>
<td>7632-00-0</td>
<td>231-555-9</td>
<td>27.6</td>
<td>15 mL</td>
<td>OX. Sol.3; Acute Tox. 3; Eye Irrit. 2A; Acute Aq. 1; H272, H301, H319, H400</td>
</tr>
<tr>
<td>Extraction Reagent B</td>
<td>Acetic Acid</td>
<td>64-19-7</td>
<td>200-580-7</td>
<td>1.2</td>
<td>15 mL</td>
<td>Flam. Liq. 3; Skin Corr. 1A; Eye Dam. 1; H226, H314, H318</td>
</tr>
<tr>
<td>Negative Control</td>
<td>Microcide III</td>
<td>--</td>
<td>--</td>
<td>0.3</td>
<td>2.6 mL</td>
<td>Skin Sens. 1; H317</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. Large spills of the solutions, controls or reagents contained within this kit are unlikely.

Personal Precautions (e.g., PPE):
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 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 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 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 specific 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 mixing Extraction Reagent A with Extraction Reagent B, 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 Reagent A</th>
<th>Extraction Reagent B</th>
<th>Negative Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sodium Nitrite (27.6%)</td>
<td>Acetic Acid (1.2%)</td>
<td>Microcide III (0.3%)</td>
</tr>
<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>8.6</td>
<td>2.4</td>
<td>7.2 to 8.5</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Soluble</td>
<td>Soluble</td>
<td>Soluble</td>
</tr>
<tr>
<td>State, Appearance and Odor</td>
<td>Liquid, yellow with no odor</td>
<td>Liquid, clear with vinegar like odor</td>
<td>Clear, odorless</td>
</tr>
</tbody>
</table>

Section 10 – Stability and Reactivity

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Extraction Reagent A</th>
<th>Extraction Reagent B</th>
<th>Negative Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sodium Nitrite (27.6%)</td>
<td>Acetic Acid (1.2%)</td>
<td>Microcide III (0.3%)</td>
</tr>
<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>Will not occur</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</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Products</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Section 11 – Toxicological Information

Acute Toxicity

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

<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</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Oral LD₅₀ Rat</td>
</tr>
<tr>
<td>Acetic Acid</td>
<td>64-19-7</td>
<td>AF1225000</td>
<td>Inhalation LC₅₀ Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Oral LD₅₀ Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dermal LD₅₀ Rabbit</td>
</tr>
<tr>
<td>Microcide III</td>
<td>--</td>
<td>--</td>
<td>Oral LD₅₀ Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inhalation LC₅₀ Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dermal LD₅₀ Rabbit</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Information</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral LD₅₀ Rat</td>
<td>&gt;5000 mg/kg</td>
</tr>
<tr>
<td>Oral LD₅₀ Rat (4-hr)</td>
<td>0.33 mg/L (dust/mist)</td>
</tr>
<tr>
<td>Dermal LD₅₀ Rabbit</td>
<td>&gt;5000 mg/kg</td>
</tr>
</tbody>
</table>
Section 11 – Toxicological Information (Cont’d)

Potential Health Effects

<table>
<thead>
<tr>
<th>Effect Type</th>
<th>Data Availability</th>
<th>Inhalation</th>
<th>Skin</th>
<th>Eyes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Corrosion / Irritation</td>
<td>No data available</td>
<td>May cause respiratory tract irritation.</td>
<td>May cause skin irritation upon contact.</td>
<td>May cause eye irritation.</td>
</tr>
<tr>
<td>Serious Eye Damage / Irritation</td>
<td>No data available</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory or Skin Sensitization</td>
<td>No data available</td>
<td>Eyes: May cause eye irritation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Generative Cell Mutagenicity</td>
<td>No data available</td>
<td>Ingestion: May be harmful if swallowed.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Carcinogenicity

IARC: Extraction Reagent A: 2A - Group 2A: Probably carcinogenic to humans (Sodium Nitrite)

These solutions, reagents or controls do not contain 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

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 the components contained within this kit.

Synergistic Effects

No data available

Additional Information

Sensitization: The Negative Control contains a small volume of a very dilute, sensitizing preservative (Microcide III). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.

Extraction Reagent A (Sodium Nitrite) – Liver – Irregularities – Based on human evidence.

Section 12 – Ecological Information

Toxicity

No data available

Persistence / Degradability

No data available

Bioaccumulation

No data available

Results of PBT and vPvB Assessment

Not available as chemical safety assessment not required / not conducted.

Mobility in Soil

No data available
Waste Disposal Instructions
Utilize appropriate personal protective equipment and spill control when handling wastes generated from using this kit. Do not discharge the solutions, controls, or reagents 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 the components within this kit.

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

<table>
<thead>
<tr>
<th>OSHA Hazards</th>
<th>Extraction Reagent A: Toxic, Irritant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative Control:</td>
<td>Sensitizer, Irritant</td>
</tr>
<tr>
<td>SARA 302</td>
<td>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.</td>
</tr>
<tr>
<td>SARA 313</td>
<td>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</td>
</tr>
<tr>
<td>SARA 311/312</td>
<td>Sodium Nitrite CAS#: 7632-00-0 Reactivity Hazard, Acute Health Hazard, Chronic Health Hazard</td>
</tr>
<tr>
<td></td>
<td>Acetic Acid CAS#: 64-19-7 Fire Hazard, Acute Health Hazard, Chronic Health Hazard</td>
</tr>
</tbody>
</table>

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>
<tr>
<td>Microcide III</td>
<td>--</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</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>
<tr>
<td>Microcide III</td>
<td>--</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Section 15 – Regulatory Information (cont’d)

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

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

H226 Flammable liquid and vapor.  
H272 May intensify fire; oxidizer.  
H301 Toxic if swallowed.  
H302 Harmful if swallowed.  
H314 Causes severe skin burns and eye damage.  
H317 May cause an allergic skin reaction.  
H318 Causes serious eye damage.  
H319 Causes serious eye irritation.  
H400 Very toxic to aquatic life.  
H401 Toxic to aquatic life.  
H411 Toxic to aquatic life with long lasting effects.

PREPARED BY: Quidel Corporation  
12544 High Bluff Drive, Suite 200, San Diego, CA 92130  
SUPERCEDES: December 2, 2013

REVISIONS: General formatting update, addition of Negative Control (Microcide III); updated Acute Aquatic Toxicity from Category 2 to Category 1 in Section 2; removed specific exposure limit data in Section 8; updated Additional Information in Section 11; updated statements and HMIS/NFPA kit ratings in Section 15; added text of H-codes and removed legend in Section 16.

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