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 H. pylori Test (Catalog #: OW009 and OW010)
Recommended Use: The QuickVue H. pylori test is a lateral-flow immunoassay intended for the rapid, qualitative detection of IgG antibodies specific to Helicobacter pylori in human serum, plasma or whole blood as an aid in the diagnosis of H. pylori infection in patients with clinical signs and symptoms of gastrointestinal disease. This test is intended for use by health care professionals.
Components: Kit is composed of individually pouched Test Cassettes, Disposable Droppers, Capillary Tubes, Positive Control (diluted human plasma containing H. pylori specific IgG) and Negative Control (diluted human plasma). The Positive and Negative Controls contain Thimerosal (<0.01%) as a preservative.

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>Positive and Negative Controls (Microcide III, 0.1%)</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 & Precautionary Statements

<table>
<thead>
<tr>
<th>Component</th>
<th>Pictogram</th>
<th>Hazard Statements</th>
<th>Precautionary Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive and Negative Controls (Microcide III, 0.1%)</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>

Supplemental Hazard Statements
Avoid release to the environment.

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>Positive and Negative Controls</td>
<td>Microcide III</td>
<td>55965-84-9</td>
<td>N/A</td>
<td>0.1</td>
<td>0.6 mL (per control)</td>
<td>Acute Tox. 3, Skin Corr. 1B, Skin Sens. 1, Eye Dam. 1, Aquatic Acute 1, Aquatic Chronic 1; H301, H331, H311, H314, H317, H400, H410</td>
</tr>
</tbody>
</table>

**For the full text of the H-Statements and R-Phrases mention in this Section, see Section 16.
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, or reagents contained within this kit are unlikely.

Personal Precautions: Use personal protective equipment, including protective gloves and safety glasses when cleaning up 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 / 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. 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 handling 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 kit specific Package Insert instructions.
Incompatibilities: To maintain efficacy, store according to the kit specific 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 (nitrile or equivalent). 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>Positive and Negative Controls</th>
</tr>
</thead>
<tbody>
<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 (H_2O = 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>6.3</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Soluble</td>
</tr>
<tr>
<td>Appearance and Odor</td>
<td>Clear to pale yellow liquid, with no odor</td>
</tr>
</tbody>
</table>

Section 10 – Stability and Reactivity

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Positive and Negative Controls</th>
</tr>
</thead>
<tbody>
<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 / 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>Microcide III</td>
<td>55965-84-9</td>
<td>--</td>
<td>Oral LD50 Rat &gt;5000 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inhalation LC50 Rat (4-hr) 0.33 mg/L (dust/mist)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dermal LD50 Rabbit &gt;5000 mg/kg</td>
</tr>
</tbody>
</table>

Potential Health Effects:

Skin Corrosion/Irritation: May cause transient irritation.  
Inhalation: May be harmful if inhaled. Causes respiratory tract irritation.

Serious Eye Damage/Irritation: No data available

Skin: May be harmful if absorbed through skin. Causes skin irritation.

Eyes: Causes eye irritation.

Respiratory or Skin Sensitization: May cause sensitization by skin contact.

Generative Cell Mutagenicity: No data available

Ingestion: May cause irritation if swallowed.

Carcinogenicity

ACGIH, IARC, NTP, OSHA: No component of this material present at levels greater than or equal to 0.1% is identified as a carcinogen, anticipated carcinogen or potential carcinogen.

Reproductive Toxicity

No data available

Teratogenicity

No data available

Specified Target Organ General Toxicity (GHS)

Single Exposure (GHS): No data available

Repeated Exposure (GHS): No data available

Aspiration Respiratory Organs Hazard

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 controls contained within this kit.

Synergistic Effects

No data available

Additional Information

No data available

Section 12 – Ecological Information

Ecotoxicity

No data available

Mobility in Soil

No data available

Persistence / Degradability

No data available

PBT and vPvB Assessment

No data available

Bioaccumulation

No data available

Other Adverse Effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
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 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 (e.g., Canada, EU, Japan, etc.), 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 Positive and Negative Control: Irritant, Sensitizer
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:
No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 3113.
SARA 311/312 No SARA hazards.

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>Microcide III</td>
<td>55965-84-9</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 product does not contain any chemicals known to 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>Microcide III</td>
<td>55965-84-9</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 Classification:  

NFPA Classification:  

Section 16 – Other Information

Microcide III  Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)

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

<table>
<thead>
<tr>
<th>H301</th>
<th>Toxic if swallowed.</th>
<th>Acute Tox.</th>
<th>Acute toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>H311</td>
<td>Toxic in contact with skin.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H314</td>
<td>Toxic if inhaled.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H317</td>
<td>Causes severe skin burns and eye damage.</td>
<td>Eye Dam.</td>
<td>Eye damage</td>
</tr>
<tr>
<td>H400</td>
<td>May cause an allergic skin reaction</td>
<td>Skin Sens.</td>
<td>Skin sensitizer</td>
</tr>
<tr>
<td>H410</td>
<td>Very toxic to aquatic life.</td>
<td>Aquatic Acute</td>
<td>Acute aquatic toxicity</td>
</tr>
<tr>
<td></td>
<td>Very toxic to aquatic life with long lasting effects</td>
<td>Aquatic Chronic</td>
<td>Chronic aquatic toxicity</td>
</tr>
</tbody>
</table>

PREPARED BY: Quidel Corporation  
12544 High Bluff Drive, Suite 200, San Diego, CA 92130  
1.800.874.1517

SUPERCEDES: December 10, 2013

REVISIONS: Addition of Microcide III at 0.1% to Positive and Negative Controls.

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